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Welcome to EAPM’s 2019 conference report

In this most interesting of years, with Brexit ongoing and the European Parliament elections on the way at the end of May, followed by a new Commission set to enter the Berlaymont in due course, we chose to focus on the importance of policy in the arena of healthcare innovation.

This was our 7th annual presidency conference and, like all the others (barring the first one held in Dublin) was situated in Brussels - close to the European Parliament and European Commission headquarters, where Europe’s ‘action’ really is.

Many of you came from far afield to descend upon the city’s University Foundation, first for an event on lung-cancer screening and then for the main conference, and we would like to thank everyone, including the management and staff at the venue for all their hard work.

You may well notice that this report varies somewhat in format to those we’ve produced in the past, consisting mainly of photographs and quotes from the event.

We’d like to take this opportunity to thank Chiara Bernini for all her wonderful support, Simon Pugh (of Simon Pugh Photography) for the excellent visuals, and Jeanne Laperrouze for gathering the quotes. Meanwhile, special thanks goes to Tony Mallett, who has worked on communications for several years now, handled the editing as well thanks goes to Emily Good and Jason Ryan for the layout.

The real stars, of course, were the speakers, sponsors and attendees. These came, as ever, from a wide range of stakeholder groups including patients, healthcare professionals, academics, industry representatives, politicians and legislators, the media and more.

We would like to sincerely thank each and everyone of you, and hope you will join us at our third annual Congress later in the year (3-5 December).

Following on from successful events in Belfast and Milan, this third edition is entitled “Forward together with innovation: The importance of policy making in the era of personalised medicine” and will take place in the Belgian capital.

The event will be held under the auspices of the Finnish Presidency of the EU, which will run from July to December.

As well as acting as a one-stop shop for all aspects of the growing field of personalised medicine, attendees and partners will be able to meet and interact with policy makers in the shape of MEPs old and new, Commission officials and Member State government representatives.

The opportunity will be firmly grasped to engage relevant Directorates-General in order to pass on needs and aims while prioritising work plans going forward, especially on the complex topics surrounding fully integrating innovation into Europe’s healthcare systems.

To aid the ongoing process, regulators, payers, investors and, of course, medical experts, patients and healthcare journalists will also be present.

Back to the conference in April and this report...
EAPM is happy say that the “Forward as one: Healthcare innovation and the need for policymaker engagement” event allowed for a bridge to legislators and others in order to further build on the developments that the Alliance has helped to architect in various policy areas.

As ever, it brought us all together under one roof, as stakeholders from every discipline and every Member State came together to forge the way ahead. The lung-cancer screening event (8 April), entitled “Saving Lives, Cutting Costs”, saw Jasmina Koeva, President of the Bulgarian Alliance for Personalised and Precision Medicine (BAPPM), give the opening address.

Among her key points were that screening is necessary and we need it now, and she added that it is at the very least surprising that the biggest cancer killer of all does not have a solid set of screening guidelines across Europe. Exactly.

Denis Horgan, EAPM’s executive director, meanwhile said: “The Alliance has long had a focus on prevention, not least through screening programmes, and, during the course of several events on the topic since its formation, we and our stakeholders have looked at the right preventative measures to ensure reliable and sustainable healthcare for the long-term benefit of patients now and in the future.”

Both Denis and Jasmina emphasised that lung cancer is one of the biggest killers on the planet, underlining the fact that action is clearly needed, and fast. We’re happy to say that the event was a great success, and you can rest assured that our conclusions will be moved on to Europe’s decision makers at all levels.

For the conference proper (9 April), Romanian MEP Cristian Buso said that: “EAPM has often pointed out to me and my Parliamentary colleagues that, while existing systems were designed and developed to support innovation and access for patients to innovative medicines and treatment, these systems are falling short and already need to be reassessed.”

He went on to say that, essentially, and demonstrably, Europe has been slow in taking account of new technologies. So, he felt, we clearly need to build a better healthcare system for our citizens and, if we build it, they will come. A major part of the building blocks for these better healthcare systems are multi-stakeholders in this brave new world of genetics, imaging, cutting-edge IVDs and more. EAPM’s plan is to create a better healthcare future for all Europeans through shared decision making and cooperation.

Also, a key aim of the conference was to allow cross-fertilisation, providing a space to let everyone share knowledge and experience, and gain a greater depth of understanding of the many and varied aspects of the field of personalised medicine.

It was also geared towards offering up valuable evidence and stakeholder opinion on which policy makers can base their decision making on how better to integrate personalised medicine into Europe’s healthcare services. As conference heard, and as you will see in this report, EU health policy is locked in to the principle that the good health of citizens is the basis for meeting the bloc’s objectives on prosperity, solidarity and safety. The two last decades have seen an explosion of data throughout the healthcare value chain as well as the advent of new platforms, tools and methodologies in collecting, storing and analysing it. The potential of Big Data in improving health is enormous. Digital technologies can empower patients, support public health policies, provide more integrated healthcare and reduce healthcare costs.

Cristian added that his fellow Parliamentarian Soledad Cabezón Ruiz, rapporteur for the amendments on the Commission’s plans to revamp health technology assessment across Member States, recently highlighted the need to have digital technologies coming into the health arena that can improve access for citizens.
Data, data, data...

The Commission, meanwhile, has said that data is the key enabler for the digital transformation and that better health data and better digital tools would lead to better quality of care and life.

The EU executive has noted that interoperability of these tools is clearly important. Especially when ensuring that electronic health records at regional and national levels are interoperable across borders.

On that topic, up to 22 Member States should be exchanging prescriptions and patient summaries by the end of 2021.

Obviously, the digital and data revolution - that’s eHealth and all other myriad aspects - are crucial to moving forward with innovation in the healthcare arena.

Overall, there is always plenty going on in the world of healthcare, which why it is vital to engage with politicians at EU and Member State levels to push the case for personalised medicine, especially raising awareness among European Parliamentary candidates old and new.

All of our events always orbit around Europe’s policy in healthcare. And with recent legislation covering clinical trials, cross-border healthcare, in vitro diagnostics and the newly introduced General Data Protection Regulation (with around 4,000 amendments) the EU is having an over-arching influence on healthcare in a growing number of aspects.

There are many challenges to providing the best available healthcare for every citizen, not least in the rapidly developing arena of personalised medicine, and the ageing population (ironically living longer due to generally better drugs and diets) is putting a huge burden on what are currently unsustainable healthcare systems.

More Europe, more-targeted policy

Time is running out for Europe to ‘get healthcare right’. And this will have to involve law- and policy- makers at all levels.

Quite aside from the moral issue of ensuring that the basic EU tenet of the best healthcare for all citizens is achieved, it is clear that more emphasis in this area can have huge benefits for the economy.

Healthcare rights must always be improved and never be eroded, and politicians need to grasp the nettle of the growing crisis over currently unsustainable healthcare systems and act accordingly.

EAPM believes in more Europe, not less in this regard, despite those Member State competencies, and also believes that politicians across the EU should try much harder to work together to find solutions, alongside the Commission and Parliament if necessary.

Politics and policies do matter, in health as in other areas, and EAPM will never stop striving to ensure that those in the legislative driving seat head in the right direction.

With the election of the new MEPs and the Commissioners, the timing of the 2019 Conference and Congress have been and will be key to positioning healthcare at the centre of any upcoming debates and policies.

Once again thank you for your involvement at every level, and we hope this report makes for some interesting reading, as well as a visual record of another excellent and productive event.
The case for lung cancer screening: Saving lives, cutting costs

Screening is necessary and we need it now. It is at the very least surprising that the biggest cancer killer of all does not have a solid set of screening guidelines across Europe.

Lung cancer is one of the biggest killers on the planet. And while there is, of course, a well-documented direct connection between the disease and smoking, non-smokers also get lung cancer. We are all aware that by far the best way to reduce numbers of lung cancer patients is to persuade smokers to stop. But not all sufferers are, or have ever been, smokers.

Lung cancer is a deadly numbers game. Figures show that lung cancer causes almost 1.6 million deaths each year worldwide, representing almost one-fifth of all cancer deaths. Within the EU, meanwhile, lung cancer is also the biggest killer of all cancers, responsible for almost 270,000 annual deaths (some 21%). In its early stage, lung cancer has a very good prognosis over a five-year period. But this becomes much poorer in later stages, because treatment by then has little effect on preventing deaths.

It is now well recognised from multiple screening trials that if early stage lung cancers are identified and surgically resected, the patient has a very good five year survival. Unfortunately, at this time, most patients are diagnosed at an advanced stage. Most experts believe that there is a strong case for lung cancer screening programmes across the EU’s Member States to reduce the cases of advanced-stage lung cancer.

More guidelines are required across the arena of healthcare, especially in screening for lung cancer. There is a need for agreement and coordination across all of the European Union’s Member States. Ideally, guidelines could help to tether costs, by bringing in improvements to the efficiency of screening methodologies and, thus, programmes themselves. Many experts believe that the EU should put guidelines in place that will allow Member States to set-up quality assured early detection programmes for lung cancer, and that there is a need for increased public-private partnerships, such as IMI II.

Among recommendations currently being discussed in European forums are the setting of minimum requirements, which should include standardised CT screening radiological procedures for low-dose imaging, risk prediction criteria for inclusion - or exclusion - for screening, together with the integration of smoking cessation programmes. Also important are improving the quality, outcome and cost-effectiveness of screening, reducing radiation risks, and thorough assessments of other risks, such as co-morbidities.

Of course, cost-effectiveness questions arise whenever population-wide screening is considered, especially in relation to frequency and duration. But a UK lung cancer screening trial has demonstrated that screening is cost effective by NICE criteria, in the modelling of their pilot screening trial. Essentially, the potential benefit of low-dose CT lung cancer screening would almost certainly see an improvement in the lung cancer mortality rate in Europe.

There is a need for the establishment of a central registry, including biobank and image bank, and preferably on a European level. On top of this, Europe’s health systems need to adapt quickly to allow patients and citizens to benefit from early diagnosis of lung cancer and reduce mortality for this lethal disease.

Now is the time to persuade policymakers across the EU that this is an urgent societal need.

And that means that it’s a political need.

Denis Horgan, EAPM Executive Director
Jasmina Koeva Balabanova, who is Chair of the Board of the Bulgarian Alliance for Personalised and Precision Medicine (BAPPM), also chaired the lung-cancer screening forum. She told attendees that there are around one billion smokers in the world, and the risk of getting lung cancer will only increase in the future. It is clearly time to go forward to reduce mortality of this disease, she said.

“Screening is necessary to improve early diagnostics, as well as the chance of survival of patients affected with lung cancer.”

Jasmina said she believes the EU should put deadlines and guidelines in place which will allow Member to implement early detection programmes.

Jorgen Vestbo, ERS Advocacy Council Chair, gave a presentation on ‘The case for lung cancer screening.’

Jorgen told the forum that we need to move away from viewing lung cancer as a death sentence, thanks to early diagnostics, survival rate can significantly be improved.

We also need to stop viewing lung cancer as a self-inflected disease and need to fight against the stigma.

“There is an urgent need to build on growing evidence and advances in technology in order to develop prevention, screening, early diagnostic and treatment for lung cancer,” he said.

Denis Horgan, Executive Director, European Alliance for Personalised Medicine, explained that early diagnosis and prevention are key so that patients can live longer.

“We must identify the barriers that policymakers have failed to tackle in lung cancer. It is important to put a focus on prevention and early diagnosis.”

He added that Europe must develop guidelines at EU level as a driver to develop diagnostic tools, prevention program and treatment.

Innovation in the field of diagnostic tools is going fast, he said, adding that harmonisation is needed across Europe on lung-cancer screening.

“We want a pilot project on such screening in Europe. This is a key opportunity to tackle the burden of the disease,” Denis said.
Harry de Koning, of the Department of Public Health, Erasmus MC, delivered a keynote speech entitled ‘Volume CT screening for lung cancer works’.

First of all, he pointed out that the average life expectancy of a late-diagnosed patient with lung cancer is 200 days, whereas it can go up to 13 years when the cancer is detected at an early stage.

"Thanks to lung-cancer screening, there is a possibility of detecting lung cancer up to 3-4 years earlier than before."

The step decision-making concerning potential new cancer screening programmes includes the establishment of evidence of effectiveness, benefits that outweigh the harms, and cost-effectiveness. Once evidence exists to support these criteria, implementation research in each country is needed to assess the feasibility of fulfilling the national requirements in practice. Harry pointed out that 1400 deaths have been prevented in the Netherlands thanks to early diagnosis. He then recapped on the now-famous NELSON trial, outlining its benefits.

He told attendees that the NELSON study presented at the IASLC World Conference on Lung Cancer, showed that annual lung cancer screening with low-dose computed tomography, or CT, in high-risk patients, reduced lung cancer deaths by 26% in men and up to 61% in women.

NELSON, he said, has made CT screening a cost-effective health intervention and opened everyone’s eyes on crucial gender differences. He added that most of the suggested cost-effective lung cancer screening scenarios will give more benefits than any present cancer screening programme.

Attendees were then told of the principles for an optimal screening strategy for lung cancer. For example, retrospective analyses suggest that annual screening might be not necessary for all those screened, and there is a need for adequate risk stratification. Those eligible will receive detailed information on the pros and cons of low-dose CT scanning, and current smokers will be scheduled a counselling visit, he said.

Meanwhile, those estimated to be below the risk cut off will be informed about the low risk, harms and relative small benefits. Butt current smokers amongst them should be referred to their GP for CVD assessment. Harry added that it has been argued that lung-cancer screening is a “teachable moment” for smoking cessation services.

Amalia Irina Vlad, of the European Commission’s DG Research and Innovation, gave a presentation on “EU research and innovation to tackle lung cancer screening.”

She told attendees that: “The lung-cancer burden (includes the fact that) five years after diagnosis, only one-out-of-six patients is still alive, with the disease often diagnosed at a late stage of the cancer.”

Tobacco is the highest risk factor, she said, adding that 26% of European citizens smoke, and the tobacco industry is investing in new tobacco products to answer the consumption changes.

But this is not the only factor, Amelia emphasised, as women, non-smokers and people between 22-40 should not be excluded from screening with low-dose CT. The forum heard about EU-funded research for lung cancer and determinants: Over the past 12 years, the EU has invested €210 million to fund 133 projects on lung cancer, as well as €98m to support 46 projects targeting tobacco.

The EU is also funding projects to complement CT screening through H2020, to support innovation in the field of early detection of cancer. She said that the EU will continue to support action to tackle the burden of lung cancer by evaluating existing screening and evaluation programmes, risk-based screening strategies for non-communicable diseases.

The EU will also continue to support complementing actions and projects to LC screening: through the iBILD software machine learning application providing additional information extracted from the CT, plus EXCITING-CT - a photon-counting, spectral silicon detector to reduce the needed CT dose, and other initiatives.

The EU, she said, is also supporting 1the one million genomes project and personalised medicine in general, while also combatting tobacco consumption, exchanging research methods and best practices through portals: best practice portals, and running the Horizon Europe mission on cancer.
SESSION I: Best practices and feasibility of lung-cancer screening to improve lives

Matthijs Oudkerk, Professor of Radiology, at the University of Groningen, gave the first presentation. He told attendees that: "Low-dose computed tomography is the only evidence-based technology for the early detection of lung cancer."

Early CT detection of lung-cancer nodules reduced mortality from lung cancer by 20%.

A risk stratification approach must be implemented, he said, to organise and implement screening, and pointed out that future decisions regarding the screening interval timing should be based on risk, psychosocial impact, cost-effectiveness and the feasibility of implementation.

Matthijs added that he recommends the establishment of a European registry for collection of screening data, because lung-cancer screening saves lives, and Europe should start planning implementation.

Jan Van Meerbeeck, Head of the ERS Thoracic Oncology Assembly, told the forum that the number of lung cancer deaths worldwide increased by 29% between 2007 and 2017, and is the 12th most important cause of death in the world.

“Lung cancer is a serial killer through a weapon of mass destruction.”

He said that it is estimated that there will be 470,000 new cases in Europe per year - that’s one new case per minute, adding that lung cancer was responsible for 390,000 deaths in 2018.

More than 50% of patients present with advanced disease will not be cured, and of those treated with ‘curative intent’, 70% will relapse. The case fatality rate, meanwhile, is more than 85%, most of these within one year of diagnosis.

Jan also spoke about gender difference in the EU in terms of lung cancer, saying it is predicted to decline among men, but to increase by 4.4% in Europe for women.

Economically, Jan said that lung cancer carries a high economic burden, and the direct cost per patient increased by 50% between 2006 and 2016. He said the cost varies according to the stage of the cancer and modality of treatment.

Jan added that there are important disparities in access to new drugs in Western versus Eastern Europe. But, he said:

“Lung cancer is the second-most preventable cause of death in the EU. And we have now an cost-effective tool to curb the epidemic in CT-scan screening.”

We have an ethical responsibility, he added.

Jan then highlighted the barriers, citing access to the highest risk groups, the false-positive rate, smokers’ stigma, radiation exposure, and of course costs.

But he pointed out that enablers were dedicated physicians willing to take up the challenge, patient advocacy groups, and experience gained from other screening programmes.

He ended by stressing the need to promote risk models to justify the CT scan, the cost, the screening and early prevention, genetic determinants, smoking habits, and other factors.
Jurgen Greibel, from the Federal Office for Radiation Protection in Germany, emphasised that: "The risk of screening must be inferior to the expected benefits.” He said that due to the typically low prevalence of serious diseases in an asymptomatic population, the vast majority of individuals undergoing screening is not affected by the disease.

These individuals do not derive a direct health effect, he said, but can only be harmed either by radiation induced cancer or by adverse health effects such as invasiveness of follow-up diagnostics, false-positive results and over-diagnosis.

He then outlined regulatory principles to develop lung cancer screening. These are the definition of risk profiles, the provision of adequate information about both potential benefit and potential risk and harm to be provided to the individual, adequate staff training and education with respect to screening, adequate equipment, and adequate protocols for the imaging exam.

Also needed is the embedding of the screening practice in a well-established screening algorithm, which in particular should include a well-established follow-up algorithm based on the results of the screening test.

Jurgen then explained that a WHO expert group is in the process of developing a document to support decision-making about regulation and implementation of screening practices using radiation in asymptomatic people.

Hans Ulrich Kauczor, Medical Director at the Department of Diagnostic and Interventional Radiology, Heidelberg University Hospital, said that lung-cancer screening made it possible to prevent more than 4,000 lung-cancer deaths in Germany.

He said: “What is required are risk profiles and models to stratify patients and risks, CT technology and low dose, plus algorithms to reduce false-positives, and a stronger policy focus on tobacco cessation.”

Anne Marie Baird, who is a Board Member of Lung Cancer Europe (LuCe), said LuCe’s purpose is to be the voice of people affected by lung cancer in Europe, advocating and networking to improve outcomes for the community. We tap into education, awareness and advocacy.

She said that: “People impacted by lung cancer matter. These are not only the patients, but also the family and friends.”

Anne Marie outlined the barriers to early diagnosis of lung cancer, and to reducing lung cancer mortality. She cited a lack of symptom awareness, normalisation of worrisome symptoms that prevent early diagnosis, a lack of understanding, fear and avoidance, perpetuation and acceptance of smokers’ stigma, and the time, travel, and cost to access healthcare, especially given the disparity between Member States.

She also highlighted the effectiveness of screening and requirements to improve the lung cancer situation, which include education and awareness, improved integration of primary care, improved equal access across Europe, shared decision making, and a Council recommendation on cancer screening.
Jan Van Meerbeeck this time chaired the session, and Pierluigi Novellis, from the Humanitas Research Hospital, Milan, told attendees that, when diagnosed at the symptomatic stage, a patient with lung cancer only have a 15% survival rate at five years.

But when diagnosed at the initial stage, they have an 80% survival rate over the same period.

Pierluigi said: "Now we know that the screening works, but it must be effective and cost-effective."

Lung cancer kills more people each year than breast, colon and prostate cancers combined, Jan said, adding that we ask the European Commission to give the same standing to lung-cancer CT screening as they have currently provided for breast and cervical cancer screening. He highlighted that the risks and harms of screening are limited if performed in high-volume centres and in centres with experience, the selection of the target population must be performed using risk models that include epidemiological and family variables, and General Practitioners must be involved in selection. Screening is an opportunity to associate a cardiovascular and pneumological check up, he said, and a vigorous smoking cessation programme. He gave an example of a programme in Milan for early diagnosis and prevention of lung and heart diseases: free-screening “Progetto SMAC”.

MEP Lieve Wierinck asked how we can include lung-cancer screening in the agenda of the European Union.

“Every patient should be granted the right to be screened when they want,” she said.

Not only smokers should get the screening for lung cancer, because there are other risk factors. However, at EU level, we can only propose guidelines for Member States to implement their own screening policy and prevention.

Her fellow MEP Jose Inacio Faria insisted that: “No money should be spared when health is at stake.”

If people have the chance to be diagnosed at an early stage, there are more likely to survive, at a lower cost, so this is all beneficial for society, he said.

EAPM Parliamentary Dinner

At the Parliamentary dinner, on 8 April, Mary Baker, Past President of the European Brain Council, opened the event saying that personalised medicine tends to focus a great deal on targeted treatment but, in general, prevention is obviously better than cure.

Mary said: “In terms of empowerment, society needs help to become more active about its own healthcare, which should be partly their responsibility.”

Better informed citizens, leading healthier lifestyles, can play a key role. Mary added that we need to involve the patients; their participation is paramount. The same goes for data sharing, but people are afraid of sharing data, we need to provide the right condition to build trust and confidence around data sharing. Denis Horgan, EAPM Executive added that “EAPM stakeholders aim to focus, not just on the delivery of the right treatment for the right patient at the right time, but also on the right preventative measures to ensure reliable and sustainable healthcare.”
Benjamin Horbach, representing Roche, told those present that today, people can enjoy better treatment, less side effects, and a more personalised approach in healthcare.

We are now the first generation to benefit from the shift from non-personalised medicine to personalised medicine.

He said: “We have sequenced the entire human genome, and the price of sequencing has decreased from 2.7 million dollars to fractions and will continue to fall.”

He explained that each cancer is complex and unique, as is each patient. But with this shift, uncertainties also arise which can slow down progress and frustrate patients and industry.

Cooperation is key to reduce uncertainties and help build a data ecosystem.

He added that what EAPM is doing is using a multi-stakeholder platform to shape the future of personalised medicine.

Denis Horgan tapped into a theme that was to resonate through the duration of the conference, namely that the patient should be at the centre of his or her treatment decisions. He said we need to empower them with more information about treatment alternatives and diagnostic and information.

The patient will be the first winner of personalised medicine take up, he said.

Peter Kapitein, of Inspire2Live is a cancer survivor and told the audience that it is the outcome of thousands of research projects that helps change, slowly but surely the healthcare system.

It is changing, he said, but we need to adapt quicker, as we adapt only when there is an urgency.

He said: “People are reluctant to change but, in healthcare, the urgency is the patient. And to put patient first is the cornerstone of personalised medicine.”

Stephane Lejeune, EORTC, told the audience that: “Today there are new treatments and screening technologies and much expectation from patients.”

But we still don’t know how to use these new technologies, he said.

Despite trials, we still don’t know how to understand things like dosage, duration and frequency, as well as the possibility of exposing a patient to toxicity and side effects, which has an impact on society.

Christine Chomienne, Director of Research and innovation, at INCa, France, said that we need to innovate our innovation, and suggested three instruments.

Data is key, and we must start to share it. We need more harmonisation, and we need to speak the same vocabulary, have the same definitions and standards so that we can better share data and our results. Technology is another enabler of course, Christine said, and so we need to continue doing research that could translate into innovation.

And we need more sharing.

Christine said: “People express their will to share their data but, in practice, it is not working yet, it is not a reality yet.”

We need to organise the way we collect, organised, process and share data, she added.
MEP Paul Rubig, who is a Member of the STOA think tank of the European parliament said that one sentence is not allowed in STOA: we never look for the best solutions; we look for the impact of technology: the economic, social, legal impact of technology to check what will be the best solutions among the regulatory options available.

He said: “We want the European legislation to be future-proof. And that applies to healthcare too.”

In Europe somehow, the lack of data sharing is killing people, he said. And Christos Andriopoulos, who is Managing Director, Merck Belgium, told listeners that progress in health care comes from multidisciplinary cooperation.

He said that personalised medicine is now a reality, it allows better prevention and better answer to disease. Unfortunately, the fruits are not equally shared.

“To bear the fruits of personalised medicine, we need to maintain the good conditions for innovation and to address the challenge of access and cost,” he said.

We need to use digitalisation as an enabler: The use of data can help better stratify patients for a better optimisation of clinical trials.

He said that 80% of the data were generated in the last 24 months, and we need to structure them, close the gap in the availability of data and allow data sharing. The EU can support it by harmonising to help better use and share of the data.

He insisted: “We have to ensure the funding and the human resources to personalised medicine so that we can meet the expectation of people and patients.”
Overview

Ask any politician, and he or she will tell you that healthcare is of primary importance to constituents - at European national and local levels. With the European Parliament elections coming up in May, there has never been a better time to underline that politics and policy matter in healthcare, especially in an ageing Europe of currently around 500 million potential patients and healthcare systems creaking under the strain.

Cash-strapped and dealing with a growth in co-morbidities among other issues, and holding their own competence in healthcare, Member States need to move quickly to make changes, cooperating, coordinating at political level to ensure ‘smart’ use of scarce resources. Each Member State and its people rely on a social contract and the basic tenets of the European Union aim to ensure equality to rights and equitable treatment across the board.

Every government has a duty to uphold these tenets and, to be fair, most do their very best to do so under often difficult circumstances. But it hasn’t been working too brilliantly. Lest we forget, the European Union has, as one of its core values, the central ideal of equality and a strong way to measure success in this goal is through the well-being of all citizens. Part of that well-being is obviously health.

But there is only so much it can do, given that closely guarded Member State competence. That’s not to say it hasn’t tried. With recent legislation covering clinical trials, cross-border healthcare, in vitro diagnostics and the newly introduced General Data Protection Regulation (with around 4,000 amendments, amazingly) the EU executive is having an over-arching influence on healthcare at least in certain aspects. To be fair, as the EU’s own legislative summary makes clear, “The EU does not define health policies, nor the organisation and provision of health services and medical care.” The EU’s role is only “to complement national policies.”

That being said, it is clearly slowly but surely having more and more influence as various EU-wide regulations are either aimed directly at health, or at least have a knock-on effect. There are many challenges to providing the best available healthcare for every citizen, not least in the rapidly developing arena of personalised medicine, and the aforementioned ageing population (ironically living longer due to generally better drugs and diets) is putting a huge burden on what are currently unsustainable healthcare systems.

Time is running out for Europe to ‘get healthcare right’. And this will have to involve law- and policy-makers at all levels. All politicians like to talk about money, or blame things on a lack of it, and quite aside from the moral issue of ensuring that the basic EU tenet of the best healthcare for all citizens is achieved, it is clear that more emphasis in this area can have huge benefits for the economy.

Health means wealth, as has been illustrated many times.

Politics and policies do matter, in health as in other areas, and Europe must never stop striving to ensure that those in the legislative driving seat head in the right direction.

Denis Horgan,
EAPM Executive Director
Martin made the key point that, if innovation cannot deliver, the potential benefits will have no effect. We need to address the crucial human factors, he said.

“If the systems that we have put in place to deliver healthcare are not able to take on board innovative solutions, there is a risk that innovation will just bring extra cost and will not be accessible to patients.”

“To ensure the maximum chances of success, we need to put the right conditions in place to ensure confidence on data.”

The DG SANTE deputy director general said that the way we use genomic data is the next step. He added that the million European genomes project is an opportunity to improve the lives of European citizens.

Mr Seychell emphasised that the patient must also have access to innovative treatment. Solutions on pricing and reimbursement schemes have to be defined and implemented.

We need to work much more together, all stakeholders - politicians, patients, and industries, he said.

There is a blame-game going on: Industry is blaming governments for not putting in place the appropriate incentives, while governments and patients are blaming the industry on pricing.

We need to find the optimal balance to incentivise R&D& innovation and implement an affordable pricing policy on personalised medicine for a sustainable healthcare system.

“Innovation is not always matching the needs of people. Impact assessments are key to see what works and what doesn’t.”

“At the top of the agenda, we must make sure that legislation is future-proof, we must be sure that we are well prepared for technological advancement.”

Mr Seychelles added that the uptake of personalised medicine in Europe is an opportunity for healthcare systems to improve and innovate. Personalised medicine can help renew healthcare systems in a patient-centric way.

Healthcare systems are often slow to adapt to industry innovation which seeks profits and return on investments, he pointed out.

Another challenge for personalised medicine is the fact that information about patients is scattered. We need an information centre with data about patients put together. Digitalisation makes location irrelevant.

He ended by saying that: “There will be a strong increase in the financial programme for 2021-27 in the Horizon Europe proposal of the European Commission as part of the next Multi-annual Financial Framework.”

This will equate to 100 billion euros, among which 7.7 billion is for health.
Overview

A major part of the building blocks for better healthcare systems are multi-stakeholders in this brave new world of genetics, imaging, cutting-edge IVDs and more.

But we need to properly harness genetic data, and there are minimum requirements for a EU-wide infrastructure to access and analyse it.

These include genomics data and clinical information standards, geared towards specific disease communities and Common Application Programming Interfaces (APIs) to enable remote data discovery and access.

Also necessary are computational resources, including secure, federated cloud-computing environments that offer secure access across national boundaries to raw data and interoperable results, as well as a repository of tools and services, including workflows used to analyse deposited data while enabling these analysis workflows to cover data across national borders.

On top of this Europe needs to take stock of lessons learned and solutions developed from existing infrastructures, and ongoing data sharing efforts in cancer, population genetics and rare disease areas.

Chair: Etienne Richer
Associate Director, CIHR institute of Genetics, Canada

Serena Scollen, Head of Human Genomic and translational data, Elixir, started by asking: “How can we understand diseases better? Well, patient stratification and personalised medicine are now possible thanks to data.”

“The more data we have about people, the better we will be able to understand the patients and the diseases.”

Europe needs to think about the scope and about the scale of data harvesting, and to develop trust of patients so that we can collect data about them, she said.

“To empower the patient, we need a strong cooperation between the patients themselves, clinicians and researchers.”

Today, the data about patients are scattered, and it is important to have access to it to limit the economic and time costs.

We need a responsible data sharing scheme: Data sharing across international borders requires policy-framing and technical standards-setting and a coordinated, secured and federated environment.

Standards are important in order to better use data for the uptake of personalised medicine, Sererena said.
Michael Hudecek, of the University of Würzburg, spoke about cancer immunotherapy with CAR-T cells. He said: “CAR-T cells represent a revolution in cancer medicine. A patient’s CAR-T cells are reprogrammed to recognise and eliminate cancer.”

As the cells recognise the tumour cells, it also prevents relapse in the long term.

Michael explained that it is a universally applicable cancer treatment that can address many types of cancers and is also transferable to infectious and autoimmune diseases.

“There is a huge medical and social value to the treatment.”

In Europe, immunotherapy with CAR-T cells is lagging behind the US and China, which are leading in this field.

There is a lack of available funding for clinical trials, while regulatory process and reimbursement schemes are not harmonised or consistent across Europe.

Fabrice André, Professor in the department of medical oncology, Institut Gustave Roussy, Villejuif, France, and an ESMO Member, explained that ESMO has a Precision Medicine Working Group regarding the evaluation and implementation of next-generation sequencing. It has several projects, one dedicated to multi-sequencing.

“We need multi-gene sequencing to identify the mechanisms of cancer progression and genomic alteration that are predictive to cancer therapies.”

He explained that this methodology allows identification of the number that needs to be tested to see which patients can benefit.

In solid tumours, he said, we are not yet at the stage of personalised medicine. It is more stratified medicine than personalised medicine.

For the moment, the benefits are small, but will increase significantly in the short-term future.

Kalle Killar, Deputy Secretary General on E-Services Development and innovation, Ministry of Social Affairs, Estonia, gave a view from her own country.

Electronic health records are important in Estonia, she said. Citizens are willing to use technology and accept having their personal data used. Data are available in different areas of our society: labour market, social, health etc.

The challenge is to reach the entire population. There’s a disparity between rural and urban areas, so the availability of data and access is unequal among regions in Estonia. The healthcare system must support and adapt to the technology that we have.

“Cooperation between public and private institutions, between physicians, scientists, patients, and healthcare authorities is key to personalised medicine.”

Basic components of personalised medicine in Estonia include patients who are willing to share data, (15% of Estonia genomes have already been harvested), a biobank, relevant professionals, and E-Health Information System.

Meanwhile, Benedikt Westphalen, of the Comprehensive Cancer Centre Coordination Molecular Oncology, University of Munich, told the conference that “the challenge for precision oncology is to make sure that we do not harm patients, and to justify decisions in front of patients and decision makers”.

“We need to all come together and build a dialogue between all shareholders. Cooperation is needed to make precision oncology a reality, which will improve diagnostics and treatment,” he said. He spoke about what is evidence in precision oncology, adding that evidence is needed to ‘Do no harm’ and justify decisions in respect of patients, regulators and payers.

Generate this evidence involves dialogue between all stakeholders, smart and innovative trial design, and the use of novel data sources.

Benedikt explained that: “Real World Evidence ‘2.0’ is required, to address fragmentation, offer a broad scope and deep details, is of a high quality, and is standardised.”
Overview

Figures suggest that healthcare costs for each patient with blood cancers reach twice the figure compared to average cancer costs. This is primarily due to the need for longer time spent in hospital coupled with more complex treatment and diagnosis. The total cost of blood disorders to the European economy was in the region of €23 billion in 2012 and is only moving higher.

Blood cancers are in the top ten of the most common forms of cancer and are responsible for approximately 100,000 deaths in Europe every year. The proportion of healthcare cost within the total economic burden is higher for malignant blood disorders than for other solid tumours.

Blood disorders are not only a burden for patients, but also for society as a whole, with about 80 million people having either malignant or non-malignant haematological disorders. CART-T cell therapy holds great promise. It is a disruptive immune cell therapy offering perspectives of survival to otherwise incurable patients.

New indications and novel methods to improve efficacy and safety of CAR-T cells therapies (and limit complications) are under active investigation but harmonisation of centre criteria, guidelines and reporting across Europe is needed. Meanwhile, collaboration and compatibility between academia and industry is important regarding standards, and an increased public awareness and research funding from the EU is necessary.

Sickle cell disease was also highlighted during the session.

Europe needs a strategy for screening for SCD that includes a programme of education about SCD in Europe that focuses on doctors and nurses and a trans-cranial Doppler scanning for stroke prevention, plus the establishment of a network of care across Europe, which would comprise of centres of expertise linked to local hospitals.

Also needed is a mechanism for identifying and tracking patients, involving screening of migrant populations and the establishment of an European registry.
Christine Chomienne, Director of Research and innovation, INCa, France, chaired this session. She explained that production of CAR-T cells requires a specific setting of cooperation between the department of oncology, haematology, physicians and pharmacists. Defining the criteria, and the standards for implementation are the EMA, and health authorities for the different steps. These are patient selection, CAR-T therapy, plus the production/ and reception of the product.

In France, a proposal was submitted to the Ministry of Health in 2018, Christine said, adding that there is a strong need for European coordination and guidelines for certification procedures, training of healthcare professionals, and communication on CAR-T Cell therapies to raise awareness.

Christine also pointed out that: “There is an opportunity to extend CAR-T cell therapies to other diseases, so not only in hematology, but more cooperation is needed.”

Michael Zaiac, for Oncology Region Europe, Novartis, said: “Hematology is at the forefront of innovation in cancer. It is like an incubator of science as discoveries can be transferable to other fields of healthcare.”

Michael added that we need to have a predictable environment in order to invest, while policymakers need to provide stability and incentives for the industry to move forwards towards personalised medicine. We also need to have a view of where incentives are going to secure our investments, and a horizon to predict the future to decrease uncertainties.

Success is a matter of collaboration, including discussions with stakeholders to bring new technologies, he insisted.

Jorge Sierra, MD, PhD, hematology, Hospital de la Santa Creu i Sant Pau, Barcelona, gave a Spanish view on CAR-T cells therapy that shows results and complications. He said that the question of how to guarantee safety is the challenge in immunotherapy, but that the current results are promising.

Jorge said: “More than 50% of patients treated with CAR-T cell therapy have not relapsed after one year, but we need more follow up to be sure of this positive outcome.”

It is a very complex and complicated therapy, due to logistics, but also due to management of patients, he said, explaining that complications include acute respiratory distress syndrome, liver failure, and neurological complications.

There are a number of requirements need for safe administration:, which include guidelines, protocols, and quality controls, as well as the experience of hematologists and multidisciplinary cooperation.

Also required are rapid access to hospital in case of complications, and available intensive unit care when this happens, and traceability of the CAR-T cells process. A survey has shown that European countries are slowly taking up CAR-T cell therapy. Spain, Belgium, France, Germany are already using it, while many other EU countries will try in the next six months.
David Rees, Pediatric hematology, King’s College London, spoke about sickle cell disease, or SCD.

He explained that SCD is caused by a mutation inducing the distortion of haemoglobin molecules in red cells, with a tendency to block and damage blood vessels. Complications are many, he said.

He revealed that sickle cell disease is the commonest cause of stroke in children in the world, 80% of children affected die in childhood in Africa, and the median life expectancy of a patient in the UK is below 60 years old.

Basic care consists of identifying affected babies through screening. England and the US apply universal screening, while in France, there is a selective screening that is operated on the high-risk population. In many other countries, David said, there is a selective screening in certain areas, but it is insufficient to detect all the cases.

“Recent migration into Europe is leading to a rapid increase of the number of patients affected by sickle cell disease and is quickly changing the situation.”

As a consequence, a high number of patients are affected that we do not know in Europe, due to insufficient screening. This means they receive suboptimal care. David emphasised that it is key to prevent child mortality. But there is a lack of facilities and expertise in countries with previously low numbers of patients with SCD.

Elvie Ingoli, President of the German Sickle Cell Disease and Thalassaemia Association, told conference that: “Sickle cell disease is the most frequent genetic disease in the world. I am a former SCD patient, cured by bone marrow transplantation when I was just seven.”

He explained that, in the sense of diagnosis and prevention of sickle cell disease, the main problem in Europe is a heterogeneous approach across countries. In some there are no centres for prevention, and prevention is done by patients’ societies. However, all across Europe there are common issues, and same struggle for patients.

These, Elvie said, include difficulties in identifying specialised healthcare facilities that are not sufficient, plus a lack of physicians’ and healthcare professionals’ training on this specific disease coupled with a lack of resources, such as specialised units, specialised physicians, and infrastructures. Also, patients are feeling isolated because they know more about their disease than their local physicians.

Elvis asked what is required at European level, and answered by highlighting the need for education of professionals, funding and harmonised guidance for SCD screening and development of tools for cross-border follow up with patients.

Also needed is increased and sustained funding for ERN-EuroBloodNet.
MEP Marian Harkin spoke mainly about innovation in general.

She explained that while existing systems were designed and developed to support innovation and access for patients to innovative medicines and treatment, these systems are falling short and already need to be reassessed.

Essentially, and demonstrably, Europe has been slow in taking account of new technologies, she said. We clearly need to build a better healthcare system for our citizens and, if we build it, they will come, but added that the coordination of social security across the EU’s Member States is a challenge.

The European Parliament has worked hard on medical trials, diagnoses and treatments, Marian told attendees. There is an increasing cooperation between Member States as a result of the current discussion in the Parliament.

Many challenges need to be tackled - the welfare of our hundreds of millions of citizens must be ensured. In particular, she said, data protection issues need to be addressed to provide the right treatment to the right patient. It is a struggle to formulate regulations that are satisfactory to society and for all stakeholders involved, the MEP conceded. But we need to continue our efforts to increase funding from the EU, develop standards, and provide training for practitioners.

She said: “Personalised medicine will only be a drop in the ocean if policymakers don’t help the stakeholders.”
To recap on regulations and policy for Part One and Two of this session: The field of regulatory affairs in the European Union is by its very nature a complex one. It is perhaps nowhere more complex than in the arena of health - and certainly extremely complicated when it comes to legislating for the exciting advances and growing expectations being brought about by personalised medicine.

The issues and regulations surrounding, for example, in vitro diagnostics, data sharing, electronic health records and pharmaceuticals are labyrinthine. Yet these complex topics need to be addressed swiftly and effectively if we are to be able to give the right treatment to the right patient at the right time while, at the same time, offering every European equal access to the best treatment available.

Under the microscope as part of this session was health technology assessment, and the European Commission’s plans in that direction. Key principles of the Commission’s moves, which still allow Member States remain responsible to draw conclusions on added value for their healthcare systems and to take subsequent decision on pricing and reimbursement, aim to address many issues and bring benefits.

Among them are high quality, timely scientific reports (including the pooling of HTA resources and expertise; providing a better evidence base for HTA across EU), and supporting evidence-based decision-making at national level. Meanwhile, patients across the EU will benefit from improved transparency and engagement in the HTA process, as well as access to truly innovative technologies, due to more timely, evidence-based decision-making. Industry, for its part, will see clearer evidence requirements, facilitating investment decisions on R&D of innovative technologies.

Chair for this session was Mary Harney, a Former Minister of Health for Ireland, and Chancellor University of Limerick.

Stephen McMahon, Co-Founder of the Irish Patient Association, told attendees: “We need to work more to ensure equity of access for healthcare, and access to innovation, for everybody across Europe.”

Many Member States have strong healthcare systems, he said, but other citizens in the EU do not have the same access to quality care.

“We need to include the voice of patients in all parts of healthcare.”

Stephen insisted that the right to consent for patients is paramount. We need to give control back to the. That's not only for surgery, and data, but also for medicine that can reduce risk.

Patients need to be empowered, was his clear message.

He said: “It is important to raise public awareness so that patients are informed about personalised medicine and targeted treatments.”

Stephen added that Europe needs to put more emphasis on the rights of patients to empower them.

“Dignity, the right to be informed, the right to consent, and the right to choose one’s treatments are paramount,” he said.
Gabriele Grom, Associate Vice President for MSD for Central Eastern Europe, told conference that: “There is probably no other region in Europe where the conference's title - “forward as one” - is so topical.

“The East/West divide in health outcomes needs to be addressed. Improving these in Central and Eastern Europe is a joint responsibility and requires collaboration amongst all stakeholders in health. Policies and policymakers play a critical role to provide the right frameworks. “

“By prioritising health, policymakers can ensure that every citizen in Europe has equal access to high quality healthcare.”

We need cooperation to secure the best healthcare outcome for patients, she said. Fewer people are dying from cancer than were doing so 20 years ago, she said, but cancer survival rates differ significantly across the EU.

For example, there is a huge gap between western and central-eastern Europe. The delay of access to innovative treatment differs across Europe, and it needs to be addressed. Gabriele explained that an innovative treatment that is accessible in one country might not be available in another country after several years. This is a death sentence for many patients.

How can we explain these differences?, Gabriele asked. Well, there is a GDP difference, but is it not the only reason for these differences. Maybe it is about prioritising healthcare on the political agenda. Healthcare spending is also lower in some countries, as a share of GDP.

Gabriele added:“Healthcare is currently not seen as an investment by some governments, but rather seen as an expense. We need to change this mindset. Health and wealth are strongly inter-linked.”

Possible solutions, attendees were told, include a EU master plan to fight against cancer, not least because health is so important for the future of a society which is ageing.

Also, investments are needed in prevention, diagnosis, screening, and treatments. Cancer treatments are far more complex than any other treatments, Gabriele said, and it is important to really address this issue. She added that health is a joint responsibility of all stakeholders that include government, industry, patients, everyone.. and we need to act so as to allow all citizens in Europe to have equal access to high-quality healthcare.

Yves Verboven, Director, Market Access and economic Policies, MedTech, spoke about the new EU regulatory framework for in vitro diagnostics, which he said is essential for the safe and effective use of a corresponding medicinal product.

There’s a need to identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.

Yves said we need put the patient at the centre of the decision-making process. This means patient empowerment.

“Informing patients about treatment alternatives, diagnosis and surgery options is crucial.”

Diagnostic information and personalised medicine are enablers for value-driven healthcare, he added. Yves pointed out that there is no European centralised market access model for medical technologies, the model used is localised, being country and region specific.

“Decisions on use and uptake of medical technologies are made at country, regional, hospital, or even at patient, level to ensure fit-for-purpose adaptation to the healthcare system,” he said.

And within the medical device market access model, less than 1% of medical technologies coming to the market every year undergo HTA, he explained. For medical technologies HTA has distinct roles which vary according to the healthcare delivery set-up of individual EU countries. This reflects the reality of patient access at national level.

Contrarily, pharmaceutical products have well established financing mechanism of pricing and reimbursement and HTA has the same role across all EU Member States, Yves explained.
Flora Giorgio, Head of Sector, HTA, DG SANTE, European Commission, also talked about health technology assessment. For the record, HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner.

It answers clinical questions such as: How well does a new technology work compared with existing alternative health technologies? For which patients does it work best?

It can also answer economic questions such as: What costs are entailed for the health system?

It is therefore a key tool for Member States to ensure the accessibility, quality and sustainability of healthcare. The Commission’s widely known proposal focuses on clinical aspects of HTA, such problem definition, and the relative safety and clinical effectiveness of a health technology as compared with existing technologies.

It seeks to address, among other issues, the fact that currently, market access for innovative technologies is impeded and distorted due to differing national or regional processes and methodologies for HTA across Europe.

This situation also contributes to lack of business predictability, higher costs for industry, delays in access to technologies, and negative effects on innovation.

Moreover, it can result in duplication of work for national HTA bodies, inefficient use of resources and limited transparency for patients.

Flora told conference: “The EU proposal on Health Technology Assessment in Europe will not address the healthcare differences among Member States. However, it will allow more synergies and more sharing of best practice and results.”

The objective of the proposal, Flora told the audience, is to reduce duplication, create more convergence and more predictability, and strengthen the quality of health technological assessment.

On top of this, it is intended to bring Member States to the same level when they take decision related to health care and technology, ensure the uptake of joint outputs in EU countries.

Flora conceded that some Member States oppose that results of the HTA be mandatory, but added that there are already amendments to the proposals made by the European Parliament in that direction.
Ortwin Schulte, Head of Unit, Health Policy, German Permanent Representation to the EU, also addressed conference on the topic of HTA.

He insisted: "There is a common interest for Member States to find a regulatory solutions on health technology assessment."

In December of last year, he explained, a letter six Member State ministers explained the red line for possible compromises on the European Commission’s proposal. It stated that HTA cannot include mandatory/binding clauses of the uptake of joint clinical assessment.

For his part, Marcus Guardian, the Chief Operating Officer at EUnetHTA, insisted that: “Member States must make the effort to seek compromise to finalise the legislation on HTA to ensure that “togetherness” becomes a reality for the uptake of personalised medicine.”

We have reached the limit of the voluntary approach, we need a mandatory approach now, he said, adding that we need to ensure that we have the proper system in place. Also, Marcus said, we need tools to help us see the future to really make personalised medicine available to patients. Cooperation is key.

Ron Van Schaik, Professor of Pharmacogenomics, Erasmus MC, President, European Society for Pharmacogenomics and personalised Therapy, ESPT, moved on to the topic of DNA. Do you have your DNA passport? he asked, before explaining that pharmacogenomics consists of finding the most-effective drug, taking into account the DNA of the patient. For the same disease, patients can have a different reaction to the medicine, such as side effects, and different levels of efficacy, he said. Also sometimes, an enzyme is not present in someone's metabolism, that prevents treatment from being effective.

The scope of pharmacogenomics is to reach the therapy window in which the drug is effective. Only 20–60% of drugs prove to be efficient. The solution lies in genetics. The key is to adapt the dosing of the drug to the patient’s DNA/metabolism to reach the therapy window so that the drug is effective.

Ron told conference that pharmacists can help General Practitioners to find the optimal drugs and dosing.

He said: “In the Netherlands today, it is possible to bring your DNA sequence to your pharmacist who will then adapt the drug dose to your DNA. Pharmacists can bridge the gap!”

The will be a conference in Seville in November 2019 to talk about pharmacogenomics, Ron explained.

“\textit{The DNA ‘passport’ is a promising tool to empower patient to improve personalised therapy and safer prescription of drugs. But we need to convince general practitioners and clinicians.}”

Martina von Meyenn, Global Medical Lead, Real World Data Platforms at ROCHE, turned the subject to real-world evidence.

She said: “\textit{A global dataset to generate rigorous real-world evidence is lacking.}”

Data are not always of good quality, or it is not clear if a patient has really given their consent. There are all sorts of obstacles to the use of data. One Roche project, she explained, is the establishment of a SMART Registry.

The vision for a SMART registry for the research sector: is to accelerate clinical cancer research, foster therapeutic innovations based on the pan-cancer paradigm, understand and define the value of molecularly guided treatment decision-making, and foster cross-stakeholder collaboration across nations and regions.

This would help to elevate the value of RWE in decision making and bring about optimised clinical processes leading to improved patient care.
The world is entering a new era for healthcare. Now patients can control their data.

Arguably, information is the main value asset of 21st century. Big Data and digital technologies are here and here to stay, and bring many benefits to the rapidly growing area of eHealth, mHealth, treatment of rare diseases and more. Medical research, clinical trials and more are generating unprecedented amounts of Big Data that is moving treatments forward in many disease areas.

Tulla Helander, Senior Specialist, at the Ministry of Social Affairs and Health in Finland, told attendees that Finland is tapping into two cornerstones for the uptake of personalised medicine, namely legislation and public data - via a public base registry.

We are in the process of integrating the data, Tulla said, adding that: “We do need governments backing the uptake of personalised medicine.”

Tulla explained that the Finnish government has set up its health-sector growth strategy, a joint initiative of the health, education and research ministries.

It includes the establishment of clusters of excellence in the field of health. Innovation occurs in ecosystems, and we are trying to create and develop an ecosystem for personalised medicine.

The Finnish government is investing 30 million euros for personalised medicine that focuses on research, innovation, education, and data management.

Tulla said that we must include people in rural areas to ensure that everyone has the same access to healthcare across the country, and spoke about the aim of establishing a national genome centre by the end of the year, with the objective of ensuring equal access to patients and in order to benefit from the use of genomic data.

She said: “Genomics is increasing our ability to identify more accurately people at risk of developing disease and to prevent diseases before their onset.”

People will be empowered to foster their own health by having more comprehensive information on the factors affecting it.

On linking the genomic databases across borders “toward access to one million genomes in the EU by 2022”, Tulla said there is a necessity to collaborate, adding that we need to build the health ecosystem in a joint venture of citizens, public authorities, universities, researchers, industry, clinicians, and the use of Public Private Partnerships.

Tulla pointed out that the system is challenged by demographic change and increasing multi-morbidity, as well as by a demand for better performance at a lower cost.

During the Finnish EU presidency we will face the current HTA challenge. We will work to demonstrate the power of sharing data for personalised medicine and healthcare and will put an emphasis on prevention.
Despina Spanou, the Director for Digital Society, Trust and Cybersecurity, at the Commission’s DG CONNECT, explained that DG Connect works on e-health, but mainly on research.

Through the Digital Single Market strategy, we try to unleash the potential of data for healthcare, Despina said, but we need safeguards which are sometimes the obstacles to the take-up of data usage in healthcare.

Digital transformation of healthcare and personalised medicine is a challenge. Trust in data usage is the main obstacle. A survey has shown that: “What prevents people from sharing data is the lack of trust - the fear that personal data may be misused.”

Despite said that, in parallel, we have some success stories on personalised medicine. We managed to have Member States sign a voluntary declaration to share data: the One Million Genome Declaration.

Meanwhile, conference heard, the challenges/objectives investment in genome sequencing, and building the infrastructure to manage these data. Overall, empowerment of patients is a driving force, and people will feel the need to share their data.

Despite spoke about the creation of Electronic Health Records, explaining that Member States have very different approaches. The idea is to have a unique standard to share data across borders, but there is already a challenge at national level with health records often not accessible across regions, she said. We need a single record on patients’ data accessible from anywhere to improve healthcare and personalised medicine.

Despoil said that the application of the GDPR is bringing more security and protection of people privacy but that we will also deploy other tools, such the use of artificial intelligence applied to personalised medicine.
Moving on...the next STEPs

In the wake of our 7th annual presidency conference, there are still many areas that need to be further developed if we are to fully imbed personalised medicine into Europe’s healthcare systems. This year’s conference was, as you know, about smart innovation in healthcare. Which is one of the cornerstones of the work of EAPM and ties in perfectly with its ongoing SMART Outlook campaign.

SMART stands for Smaller Member states And Regions Together, and involves an on-the-ground approach and presence to help to integrate personalised-medicine concepts into national healthcare systems.

While most people accept that innovation is good for citizenry, many question the perceived high prices charged by pharmaceutical companies for certain medicines. Prices that many Member State healthcare systems cannot pay. The knock-on effect, of course, is that many patients are denied novel drugs and/or treatments, leading to a lower quality of life and sometimes avoidable death.
Smarter integration across Europe of current science into healthcare systems, allowing much more preventative and targeted care, would represent a form of value that any citizen could see.

Add to this the fact that a healthy Europe means a wealthy Europe, not least because of outside investment in groundbreaking research and cutting-edge science, and there’s more clear value for everyone.

But one major question for society and, therefore, the EU and its Member States, is how to realise the massive potential being offered by research and development, and the incredible advances in the medically applicable sciences?

Essentially, we have to find better and faster ways to do this and the barriers, while substantial, are far from being insurmountable. Certainly, the current system is far from perfect, but that doesn’t mean that we should leave innovation to lie down in the grass when it should be soaring to new heights for the benefit of EU citizens.

Paul said: “Right in front of all of us, whether in easter, western, northern or southern Europe, are issues that are universal. These include genomics, regulatory frameworks in terms of incentivising innovation, HTA, and public private partnerships.”

“In the end, and in order to provide the optimal platform for smart innovation in healthcare, it is clear that Europe needs to develop a coherent message on innovation,” he added.

Meanwhile, closing the conference, Croatian MEP Dubravka Suica pointed out that our work to imbed personalised medicine into Europe’s healthcare systems is really only just beginning.

That’s despite all the work of EAPM, despite all the work of the European Parliament, despite the important contributions of all of the stakeholders here, despite the efforts of researchers, academics, industries, patients’ groups...and despite all of the scientific genius across the EU, and the innovation in the regions. There is much still to be done to build a better, healthier world for all our citizens, Dubravka said.

She felt sure that Croatia’s presidency of the EU will be doing its own part when it takes its turn to lead the European Council at the start of January next year but, like those that have come before and those that will come after, it has a big challenge.
CONCLUSIONS
And finally...

In the wake of the conference, and at the end of this report, it is of benefit to quickly recap on EAPM’s STEPs programme - which stands for Specialised Treatment for Europe’s Patients.

So, here we go...

**STEP 1**
Ensuring a regulatory environment that allows early patient access to novel and efficacious personalised medicine

**STEP 2**
Increasing R&D for personalised medicine, while also recognising its value

**STEP 3**
Improving the education and training of health care professionals

**STEP 4**
Supporting new approaches to reimbursement and HTA, required for patient access to personalised medicine

**STEP 5**
Increasing awareness and understanding of personalised medicine

Since we launched in March 2012, just over seven years ago, the above have been our over-arching goals. Much has changed since then, but much remains the same.

As the Commission and the upcoming representative of the Finish Presidency of the EU emphasised at the end of this year’s event, the circumstances are ripe for change, and the future will rely on what we create not just tomorrow but in the here and now.

Despite a lot of progress made in the last five-year legislative period, and our hopes for the next, one thing remains abundantly clear - we need more involvement of the EU in healthcare.

That’s what the majority of Europe’s citizens say they want.

And that, in the end, means more collaboration, more cooperation, less silo thinking, more engagement, more and better use of smart resources, more innovation, more investment, more of everything.

Personalised medicine used to be little more than a dream. But now embedding it into the EU’s healthcare systems, utilising all this potential for innovation, is getting closer by the day to becoming a reality.

So, we can’t stop now.
Since its formation, EAPM has always engaged with policymakers in the European Parliament, the Commission, and at Member State level to further the goals of personalised medicine.

This will continue throughout what is an important year, with the European elections and new commissioners entering the Berlaymont. In tandem, we will also engage with EU countries as part of a series of high-level roundtables on healthcare policy, now and into the future.

These upcoming pan-institutional events are indicative of the emphasis placed by the Alliance and its stakeholders on policy in healthcare.

POLICY MATTERS!

For further information, email EAPM via Chiara at Chiara.Bernini@euapm.eu