The EAPM Conference under the Croatia Presidency, “Defining the healthcare ecosystem to determine value”, on 24 March 2020, broke new ground in more ways than one. As with previous EAPM conferences, it advanced the agenda on personalised medicine in key areas of current concern – and attracted more than 200 participants, including 18 Members of the European Parliament, along with EMA representatives, and speakers from the European Commission’s DG SANTE, DG Connect and DG Research.
But this 8th annual conference was innovative in another way. It was originally scheduled to be held ‘live’ in the Belgian capital of Brussels, but in the face of the Covid-19 crisis, EAPM reworked the format and held it online, to overcome the continent-wide border closures, travel bans and lockdowns. So, fittingly, in the week marking the 25th anniversary of the Schengen agreement that opened Europe’s borders, EAPM could still bring together its customary wide range of participants from across Europe - patients, scientists, clinicians, researchers, policy makers, key national representatives, journalists and more - and maintain its tradition of interactive sessions among stakeholders to promote the precise identification of challenges and the building of consensus.

**Investment**

Among the many challenges identified in the course of the meeting, the need for investment emerged as one of the priorities – public investment in health systems to provide the assets that drive scientific advances, infrastructure for continually improved access to medical care, informed citizens benefiting from actions on prevention, screening, early detection and diagnosis, and inbuilt resilience not only for sustainability over time, but also to withstand shocks. Specific aspects highlighted during the conference ranged from forging links between biobanks or validating and integrating biomarkers to the take-up of innovation in technology and

**Incentives**

Another of the themes that underlay much of the discussion was the role of incentives as drivers of human, scientific, and economic behaviour. It is not enough, it was acknowledged, to rely on the spontaneous take-up of opportunities, whether it be for citizens to modify their life-styles, for hospitals to cooperate in data-sharing, for the private sector to pursue product development that can answer unmet need, or for national health and care systems to adapt their procedures to changing demographic and technological realities.

**Covid**

In addition, the initial agenda for the conference, with its accent on keeping the focus on the person in evaluating personalised medicine, was expanded to also take on board discussion of the immediate and longer-term challenges that Covid-19 is posing for healthcare in general and personalised care in particular. There was a clear interest - and consensus - in EAPM bringing to bear its wide stakeholder engagement in building bottom-up recommendations in the context of a post-Covid-19 healthcare world.
Opening session:

Healthcare in the coronavirus crisis

With Covid-19 sweeping across Europe at an increasing pace, the ability of healthcare systems to respond was inevitably in the forefront of everyone’s mind. A poll taken among the participants at the start of the conference showed broad if unenthusiastic support for the EU’s efforts so far in tackling the outbreak, with 58% saying it was satisfactory, 17% saying it was good, and just 1% very good, while 25% rated it bad. Asked how the EU should support member states, most (43%) favoured ensuring the development of essential medicines and diagnostics, with reallocation of medical equipment and financial support each backed by 17%, setting and ensuring compliance with guidelines 13%, and the reallocation of medical stuff 10%. Asked what they saw as priorities, most respondents highlighted access to treatment (42%), followed by access to testing (29%), access to innovative health care (23%) and access to more information (6%).

Testing and treatment

The emphasis given to testing and treatment at the conference sprang both from the obvious necessity in the face of the current crisis, and from the agenda itself - since testing is such a central aspect of personalised medicine. Indeed the conference devoted specific sessions to biomarkers and molecular diagnostics, and to prevention and early diagnosis, exploring among other things how to best explain to patients and society the need for both clinical research and ongoing data collection, and the particular benefits in the context of Covid-19. But the questions around testing were also reflected throughout the broader discussions of personalised medicine, the outstanding challenges in orphan medicines development, and how to better exploit the potential of big data.

Questions ranged over the immediate issues of who to test, when to test, and how to test, what resources are needed, who will conduct the tests, and what systems are needed for analysing and for providing feedback loops to decision makers. Views were exchanged on what sort of testing and treatment pathways might be promoted for this novel coronavirus.

As Benedikt Westphalen, Koordinator Molekulare Onkologie at the Comprehensive Cancer Centre of the University of Munich, emphasised, there is an overwhelming need for quality in testing, and the development of minimal and optimal testing requirements should be considered.
Healthcare in the coronavirus crisis

Restoring Health-care Systems after the Crisis
Longer-term issues were explored too. In very concrete terms, these covered the restoration of effective healthcare systems at the other side of the crisis, after so many cancelled surgeries, including psychiatric support and economic support for additional treatment. And on a more conceptual plane, they also covered what sort of strategic re-orientation of health system thinking could future-proof healthcare, to ensure greater preparedness. Central features of this discussion were the merits of a sharper focus on earlier detection, optimised use of data, more precise diagnosis and faster therapeutic and preventive responses. Also taken into account were the numerous related issues of product evaluation and assessment, more robust supply lines, communication and health literacy, and the relation between private and public sectors.

Gaps
The exchanges saw accusations from patient representatives that EU health systems are “inherently irrational”, lacking clear objectives and action plans, links between inputs and outcomes, systematic measurement of patient reported outcomes, and systematic tracking of costs to patients and to society. Healthcare systems “have inertia that impedes the use of innovation.” Antoni Montserrat Moliner, a former EU official and now an advisor on public health, perceived a decline in strategic planning on health issues within the Commission in the last decade, leaving wide gaps in current provision and foresight, and leaving open the question of where the EU should act - and where it is authorised to do so.

Filling the Gaps
But the main questions underlying the debate were not so much how far the EU is unprepared for this health crisis, but what needs to happen for it to be able to manage further crises, and for the general health of healthcare systems to be secured for the future. Is the lesson of the crisis that the EU would be better able to respond with greater powers over health, and with greater integration of health policy with other EU policy fields - ranging from data governance and macro-economic management to freedom of movement? Is health policy formation in the EU stuck irremediably in grooves that prevent a comprehensive view of what is needed for an effective and sustainable and future-proofed healthcare system?
Healthcare in the coronavirus crisis

Working Together
Are national hesitations over exploiting advances in science, technology and innovation compromising the EU’s overall chances of building new systems to tackle new demands? Are the evident national differences and divergences in everything from healthcare funding to clinical guidelines compatible with a European ability to provide for and protect the health of Europe’s citizens? Is the EU capable of recognising the risks posed to health by persistent inequalities, between and within countries, in economic, social and health? Can it hope to meet new challenges without some provision for permanent contingency planning and reserves of assets? And can it learn to move faster in pursuit of an urgent common goal, as WHO’s Dr. Michael J. Ryan urged in late March: “Be fast. The virus will always get you if you don’t move quickly. And you need to be prepared.” In his view, the main problem for health authorities at the moment is “everyone is afraid of making a mistake... but the greatest error is not to move, the greatest error is to be paralyzed by the fear of failure.” Ivana Cattaneo, Public Affairs Director, Novartis Oncology Europe, claimed that Covid-19 shows “we have to share, cooperate, integrate systems.” It is, she said, “an opportunity to drive policy and change.” Ivica Belina, President, Coalition of Healthcare Association, insisted with equal force that the EU needs to be more active on healthcare, both in terms of preparation for sudden emergencies such as Covid-19, but also in boosting overall healthcare system capacity to ensure adequate provision for patients needing treatment both during and after a crisis.

Collaboration
EAPM’s executive director Denis Horgan, who chaired the conference throughout the day, put the issues clearly on the table in his introduction: “Europe and, indeed, the rest of the world, is facing a serious challenge with this highly contagious and dangerous virus. The need for pan-EU coordination and cooperation between Member States, the European Commission and the European Parliament in healthcare has never been more obvious, nor has the need been greater for us to work together to swiftly integrate innovation into healthcare systems.”

Indeed the theme of closer and better collaboration became the leitmotif of the discussions throughout the day, with encouragingly wide agreement that across the range of healthcare activity, stretching from early research to European governance, there is scope and even the need for much more sharing and cooperation in the face of the current challenge to the now highly questionable status quo. As one panellist expressed it: “A fragmentation culture is no longer acceptable.”
German MEP Tiemo Wölken said that the Covid-19 outbreak demonstrates the need for greater collaboration on healthcare matters across the continent, and that it highlights the need for member states to work more closely together on coordinated measures at an EU level. “I hope that some member states that insist on subsidiarity learn from this outbreak and change the way that they make decisions.”

Ivica Belina – speaking from Zagreb in the immediate aftermath of the earthquake there – welcomed moves he saw towards cooperation within the pharmaceutical industry in pooling of research for vaccines and treatments against Covid-19. He also called for increased and systematic dialogue across all stakeholders to improve take-up of innovation in medical practice, with the adoption and implementation of patient pathways and best practices.

For Benjamin Horbach, Health Systems Strategy Leader on Personalised Healthcare at Roche, multi stakeholder collaboration is central. Working closely with all partners would be key to help realize the impact of the transformation of health systems and improve patient access to care. Member states can benefit from the work of the Commission and the European Parliament and leveraging the learning available from clinical practice and decision making.

Bengt Jonsson, Professor Emeritus of Health Economics at the Stockholm School of Economics, asked pointedly whether the EU has done all it can to cooperate in R&D and health: “There is not enough collaboration,” he said.

Tuula Helander, Senior Advisor in the Finnish Ministry of Social Affairs and HealthPermanent Secretary’s Cabinet; and Secretary General at the Finnish Cancer Institute, illustrated how cooperation at national level among ministries responsible for economics, employment, health, education, and finance, together with academic institutions, had made it possible to create Finland’s integrated approach to cancer and personalised care, deploying its genomic testing strategy. “Integrating genomics into healthcare is a joint venture of different sectors and stakeholders, authorities, researchers, companies and citizens,” she said.

The sentiment was reflected throughout the day in calls for common approaches to everything from databases that can be shared among different stakeholders to agreement on improvements in the deployment of PSA testing.
Healthcare in the coronavirus crisis

Consensus Outcomes:

Pan-EU coordination and cooperation in healthcare has become even more vital - and this gives new impetus to EAPM’s wide stakeholder engagement to promote the integration of innovation into healthcare systems in a post-crisis Europe.

The development and deployment of more refined testing techniques is crucial to advancing personalised medicine and better health.

Some countries have shown the way in national integration of research and care, and some companies have shown a new readiness to work together in research, but this trend merits wider support and follow-up.
The objective of patient access to biomarkers and molecular diagnostic technologies is well-established. The value for patients lies in receiving safer and more appropriate and effective therapies, as well as increased confidence and certainty in their treatment decisions, while physicians would be better informed to make the best possible individual treatment decision for their patients, and payers would see more cost-effective healthcare and better budget allocation. But what is lacking is a comprehensive policy framework to implement this, in the face of variations in national processes and procedural requirements, and insufficient resources. Marisa Papaluca, Visiting Professor at Imperial College London, who moderated the session, introduced the session with the observation that health is “a political issue, and we are all in it together.” Effective testing requires putting personal data into context, including the social context, she insisted, calling for the removal of the barriers between research and clinical care, and for making all knowledge available systematically at population level.

An audience poll at the beginning of the session sought opinions on what should be put in place to have better biomarker testing. This revealed most support (38%) for reimbursement, followed in descending order by infrastructure, guidelines, and healthcare workforce. The principal value of testing was to reduce disease burden for 59% of responses, against 22% for reducing treatment costs and 20% for reducing the risk to society. People’s personal wishes to learn from the test indicated a majority for knowing if they are at risk (43%), knowing if they can anticipate clinical care (37%), and knowing if they are at an early stage of disease (20%).

Discussion highlighted the many continuing areas of uncertainty: over which test to do, and when; whether the test is reliable; and what action should follow, for the patient, the physician, or for public health and society. The need was emphasised for comprehensive data collection to exploit the predictive capacity of biomarkers. Major elements in the exchanges were the need for investment in access to biomarker testing – relating to infrastructure, funding and education – and issues of interoperability, collection and sharing of data, scientific engagement, quality assurance, and cooperation with the clinical level. Other questions that arose included whether the introduction of biomarker testing in clinical care crossed the traditional ethical distinction between care
and research, and how far it was appropriate to be proactive in using the information from pharmacogenomic profiling of healthy individuals.

According to Paul Naish, Global Director, Oncology Advocacy and Government Affairs, AstraZeneca, the big challenge is to ensure that patients across Europe have access to the right testing at the right time. “Addressing barriers to this needs more attention in the EU debate,” he said. He offered the example of targeted treatment improving the clinical outcome in advanced ovarian cancer through testing for BRCA – “if we can identify patients”. Testing at diagnosis ensures information is available to support decisions on appropriate treatment, he argued – adding the warning that delays in test results can block access to some treatments. He alluded favourably to efforts at developing consensus over the last two years on minimum and optimal testing requirements, but pointed to continuing implementation challenges in testing – particularly in crisis situations, such as the current pandemic, the recent earthquake, or across large territories with scattered populations. “The gap between theory and practice is large between and within countries,” he said.

Beata Jagielska of the Polish Alliance for Personalised Medicine reported on the efforts to finance genetics testing in Poland, where about 22,000 people suffer from lung cancer each year and the same number die from it. But there is also underuse of testing because of lack of awareness and training among physicians. “Europe is behind the US in testing and, because advances can’t reach a patient who isn’t tested, the EU needs to fill this gap,” she said.

Stefan Gijsels, Executive Director of Digestive Cancers Europe described the current 600,000 annual death rate from colorectal cancer as a “massacre - and most preventable”. But, he said, although there are tests, they are unused: only one member state does screening for colorectal cancer correctly, he said.

Another patient representative, Alastair Kent, the former director of Genetic Alliance UK, acknowledged the advances in precise diagnosis from gene sequencing, biomarkers, and greater understanding of disease at molecular level. But he insisted that the data needs to be channelled so that it cascades into action. “Diagnosis is not enough”, he said.
Bettina Borisch of the BioCampus at the Institute of Global Health in the University of Geneva, emphasised the need to move not just from diagnosis to treatment, but onwards to prevention as a policy issue, mirroring the evolution of the 19th century physician Rudolf Virchow from pathology to public health to politics. She also entered a firm plea to avoid putting public health and clinical medicine in separate silos: “Our borders in Europe are artefacts of 19th century history and we need to overcome them in our discussions,” she said.

There was strong support for molecular diagnostics from Tiemo Wölken too. He said: “The value for patients lies in safer and more effective therapies, as well as increased confidence and certainty in their treatment decisions. Physicians, meanwhile, would be better informed to make the best possible individual treatment decision for their patients, and payers would see more cost-effective healthcare and better budget allocation.”

And Antoni Montserrat called for a common European framework on the screening of newborns, pointing out that some countries screen infants for a mere two congenital diseases, while others look for as many as 42.
Consensus Outcomes:

Biomarkers and molecular diagnostic technologies lead to safer and better treatment, better-informed physicians, and more cost-effective healthcare.

Investment in biomarker testing will be needed for the comprehensive data collection that will allow full exploitation of the predictive capacity of biomarkers.

Testing must be considered in terms of not only what to test, but when to test and who to test.

Test data should cascade into action: diagnosis is not enough.
Working session 2

Prostate Cancer – Prevention and Early Diagnosis

The general questions over testing were explored in the particular context of prostate cancer, where controversy has broken out over the value of the standard prostate specific antigen (PSA) test. The number of men being diagnosed with prostate cancer across Europe has increased over recent years, with some 3 million Europeans living with the condition, with significant differences in incidence between Member States, and with an annual death rate of around 100,000.

According to a poll of the audience, early testing should be a priority for men’s health for 83%, with 3% saying no and 15% undecided. As to what could influence the decision to take part in a cancer screening program, 82% said information about usefulness of screening and early diagnosis, 11% said cost, and 8% said convenience in terms of proximity. Factors such as expertise and skills of healthcare workers or the safety and quality of the equipment did not enter into the equation. And asked whether sufficient written information regarding cancer diagnosis and possible treatments is available to patients, 66% said no, 11% said yes, and 23% said they did not know.

Moderating the session, James N’Dow, Guidelines Office chair at the European Association of Urology, rejected any notion that prostate cancer should be seen as a second-class cancer, and warned that the controversy over screening has to be resolved urgently to avoid damage to men, and also to their families.

Hendrik Van Poppel of the University Hospitals of KULeuven, and EAU Adjunct Secretary General for Education, insisted that PSA has been effective in cutting mortality through early detection: “We do not need new screening trials,” he said, citing studies showing reductions of 21% and 44% in deaths as a result of screening. Early detected disease can be cured, and treatment of early disease has fewer side effects; by contrast treatment of more advanced disease has more side effects and often fails to cure comma and treatment of metastatic disease is extremely expensive. He said recent discouragement of testing on the grounds of overdiagnosis and overtreatment was “anti-PSA propaganda”, pointing to rises in mortality in the UK, the USA and Germany after falling testing rates.
The key, he argued, was to develop the ability to discriminate between significant and insignificant cancer, taking account of age, density, and velocity in testing, and wider use of molecular biomarkers and risk calculators, as well as the use of MRI before biopsy.

**Jan-Willem van de Loo**, from the Health Research unit in the Commission’s Research and Innovation DG, confirmed that funding was earmarked for cancer research in the forthcoming Horizon Europe programme, and that prostate cancer prevention would be addressed in the EU’s Cancer Mission, and perhaps in the Beating Cancer Plan, although he could not yet be precise about what shape that would take.

**Anders Bjartell**, Professor in Urology in the Dept of Translational Medicine in the Medical Faculty at Lund University, and Senior Consultant in the Dept of Urology at Skåne University Hospital, acknowledged that there had been a shift in Sweden from the 2014 rejection of PSA to readiness to investigate organised PSA testing in 2018, making use of new refinements. He spoke of “a shared responsibility to improve diagnostics, to identify the best algorithm to reduce over diagnosis and overtreatment, to incorporate imaging and biomarkers, to use artificial intelligence and digital digitalization to make it minimally harmful and more cost effective.”

**Hans Peter Dauben**, Secretary-General of the Rheinische Fachhochschule in Cologne, conceded that despite his earlier scepticism, he recognised the need for PSA testing to be more organised, while taking account of different approaches in different countries and regions. **Maria Ribal**, Head of the Uro-Oncology Unit in the Hospital Clinic of the University of Barcelona, reported strong opposition to PSA testing in Catalonia, but offered a proposed flow chart to reduce the risk of overdiagnosis and overtreatment. Data presented by **Erik Briers**, Europa Uomo, showed PSA delivering a rising level of diagnoses following biopsies over ten years in Belgium, to 72% positive, capturing a high level of stage 1 cases among men in their late sixties. The exchanges highlighted the common desire for early diagnosis – an objective that already features in EAPM’s proposal for the revision of the EU’s 2003 Recommendation on Screening.
Consensus Outcomes:

A rise in the incidence of prostate cancer in Europe has coincided with controversy over the value and use of the standard PSA test.

Resolution of the controversy requires a shared responsibility to improve diagnostics so as to reduce the risks of over-diagnosis and overtreatment.

Upcoming EU initiatives on research and cancer screening may offer a pathway to improved PSA screening.
Orphan Regulation and Personalised Medicine

The conference took place as the European Commission was finalising its long-awaited internal working document on the performance and possible modification of the EU's orphan medicines scheme. The evident success of the scheme in stimulating the development of products for rare diseases has become bound up, to some extent, with the EU’s discussions on personalised medicine, since orphan medicines, by their nature, raise many of the same issues as the development of personalised medicine. The interplay prompted reflections on the comparisons and contrasts of two concepts.

A poll of the audience indicated that 89% did not believe that orphan medicines and personalised medicine are the same; nobody replied yes, but 11% said they had no idea. Asked what will be needed to keep advancing innovation in personalised medicine, 15% said public private cooperation, 13 percent said translational research, 9% said funding, and 6% said shared decision-making including patients; but 57% said all of the above. Bringing clarity of understanding between orphan medicines and personalised medicine may help advancing research and access to innovative treatment, believed 73% of the audience, while only 10% said not. 17% had no opinion.

Kaja Kantorska, from the European Commission’s DG SANTE, pointed out that there was no official EU definition of personalised medicine, whereas orphan medicines are defined by the EU regulation that set up the incentives scheme to promote their development – although of course, she added, personalised medicines can be eligible for the scheme. Looking ahead to the imminent publication of the Commission’s sector working document, she said it would “reply to how the scientific environment has evolved and to what extent the orphan regulation is still relevant. This will include whether the therapeutic indication for gene therapy should reflect the mechanism of action of the product, and whether it fits with the current definition and interpretation of the orphan condition, and how to define orphan conditions for tissue agnostic treatments.”

Personalised medicine is needed to redress dysfunctions in the health system, it was argued by Stefan Gijssels. “The right treatment at the right time would have an impact on overall survival and on quality of life and
would create clarity for patients in times of uncertainty.” Bengt Jonsson saw inescapable conditions in developing personalised medicine: innovation based on private and public research, investments in infrastructure for production, quality control and storage of data, and in information and incentives for making the right choices for testing and treatment, on private and public research, investments in infrastructure for production, quality control and storage of data, and in information and incentives for making the right choices for testing and treatment.

Simone Boselli, Public Affair Director at EURORDIS, recognised that the orphan medicines scheme had done more than merely promote the development of 170 products, but had also prompted valuable cooperation cross-border. The criticisms often levelled at industry for leaving many areas of unmet need should be nuanced, he said, in light of the confounding factor of divergent national authorities’ interpretations and practices. And he welcomed Covid-19 research in the context of orphan drugs as a “massive exercise in repurposing drugs”, since Eurordis has long backed such an approach for rare diseases. “You have multi-arm trials, multi-country trials running in parallel, testing different drugs and repurposing specific drugs that have already proven their safety in in other areas.” And as session moderator Ivana Cattaneo, Public Affairs Director of Novartis Oncology Europe, concurred, “I hope we are going to incorporate the learnings from Covid-19 in our other activities.” She added that while the overlaps between orphans and personalised medicines could lead to some confusion over definitions, discussions of this nature were of value in helping to bring clarity.

Maciej Gajewski, Head of International Government Affairs & Policy at Alexion, also offered a warm assessment of the scheme as “of critical importance for orphan drug manufacturers”. He said Alexion relies heavily on the regulation in view of its focus on developing medicines for rare diseases, and warned against potential modifications that would weaken its incentives. The pandemic impact will create a new environment for discussing rare diseases and orphans and personalised medicine, he predicted. For Benjamin Horbach, closer partnering around health systems will be necessary to improve patient access to personalised care.

The discussion of personalised and orphan medicines inevitably extended into issues of payment, too. For Bengt Jonsson, “the biggest challenge for implementation for precision medicine now is not the science but the economics. The three biggest barriers to precision medicine are reimbursement, reimbursement, reimbursement.” He argued that the new
WorkShop 3 - Orphan Regulation and Personalised Medicine

evidence landscape involves more alternatives, more choices, and increased need for evaluation, because of its range of different trials, comparative effectiveness research, reviews of evidence, health technology assessment, and mechanisms such as evidence based medicine and coverage with evidence development. Modelling the cost effectiveness of testing and treatment will be more complicated and demand more data – including particularly real-life data, since randomised clinical trials and guidelines may not mirror clinical practice. Valuated in terms of outcome and costs and there are several possible strategies, data, since randomised clinical trials and guidelines may not mirror clinical practice. Valuated in terms of outcome and costs and there are several possible strategies.

The discussion is timely, since the current disruption from Covid-19 could open the gate to a re-alignment of priorities to evaluate the needs of patients, healthcare professionals and health systems in terms of improved and safer therapies, including enhanced collaboration between EU regulatory and payer groups. This would have the aim of identifying core outcomes other than survival that can be incorporated into trials, as well as healthcare systems, to generate data throughout the lifecycle. This could prevent the most transformative therapies being undervalued by out-of-date value frameworks. The search should begin in earnest for an agreed European (and possibly global) approach to quantifying clinical benefit, with clinical outcomes other than survival that can be agreed upon to be used in registration trials and healthcare systems.

In terms of the current discussions in Europe valuation, the conference also heard views on the attempt to agree closer coordination on health technology assessment, where the Commission proposal is currently still stuck in the Council. Tiemo Wölken, who is responsible within the European Parliament for this subject, said he was hopeful that Germany might secure a breakthrough during its presidency later in 2020. “It is time for it to become mandatory. It’s time for more binding measures”, he said, arguing that it will improve predictability and planning of healthcare systems for all parties across the EU. At the same time, his compatriot Hans Peter Dauben cautioned against “a Brussels fiat”: health technology assessment can only make an evaluation in a specific setting, and local conditions and decision-making must be respected.
Consensus Outcomes:

Reflection on the comparisons and contrasts of orphans and personalised medicines should clarify policymaking at a time when both concepts are under new scrutiny.

The right treatment for the right patient at the right time would not only boost survival and quality of life but would provide patients with new certainty.

Companies working in orphan medicines are apprehensive about the potential risks to incentives from impending legislative change.
Coordination and support is needed to develop cross-border solutions for sharing expertise and linking genomic and other health data. At the heart of genetics-based personalised medicine - aimed at giving the right treatment to the right patient at the right time - lies the collection, storage, use and sharing of data. To make the most of all the massive amount of valuable information flowing into super computers and biobanks there needs to be a shared vocabulary and data-set standards, with agreed universal protocols for sending, receiving, and querying the information.

A poll of the audience revealed that 90% would be prepared to share personal health data for research purposes under robust and ethical circumstances, while 3% said no and 8% were undecided. For 21%, their national health system accepts real world data for drug approval or funding decisions; for 18% it did not; and 62% said they did not know. The biggest barriers in sharing data between healthcare systems were seen as lack of trust by 41%, lack of infrastructure by 30%, lack of standards by 25%, and lack of human resources by 5%.

The session moderator, Niklas Blomberg, the Director of Elixir, favoured the development of common standards for data quality, security, interoperability, privacy, and ethical guidelines, as well as governance models underpinning the establishment of sustainable cross-border digital infrastructures and networks for genomics and personalised medicine in Europe. Resolving questions over how to connect resources across national and organisational borders will depend on distributed learning where the tools go to the data rather than the other way round, as well as on developing the skills and capacity to drive value genomics and big data in European healthcare. It will also need a broad acceptance for data sharing with the public. He spelt out the plan for a federated European healthdata area that would make use of European research data from the genome, the phenome, clinical trials, clinical data, electronic records and imaging,
and exploit it through a federated cloud computing environment that offers secure access transnationally.

Ceri Thompson, Deputy Head of Unit eHealth, Wellbeing & Ageing in the European Commission, highlighted the role of the promised European health data space - to promote health data exchange and to support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. She said that better healthcare, better policy making and better research and innovation will be achieved through mechanisms for governance, quality of data, and infrastructure. Governance will include legislative and non-legislative measures and rules for primary and secondary use of data respecting general data protection regulations, along with a regulatory framework for artificial intelligence focused on trust. Quality of data will result from the uptake and development of the European Electronic Health Record Exchange Format and FAIRification of health data for primary and secondary use. And, she foresaw, Horizon 2020 will include projects to support genomics, health data interoperability and the next long term financing framework for the EU.

Toni Andreu, Scientific Director of EATRIS, depicted the biomedical innovation pipeline as broken, with poor levels of reproducibility of data, and consequent high failure rate of clinical trials at Phase II. He emphasised the need for more testing of higher quality. Andres Metspalu, professor of Biotechnology and Head of the Estonian Biobank in the Institute of Genomics of the University of Tartu, counselled the use of a genomics approach to estimate disease risks so as use the data for early preventive measures, including for common diseases such as breast cancer or type 2 diabetes. For Mark Lawler, Chair in Translational Cancer Genomics Centre for Cancer Research and Cell Biology, Queen’s University Belfast, interoperability is key – and “Covid-19 shows we need to be able to respond quickly and address any slowdowns from data transmission.” He sees the need for a new data enabled research cooperative involving patients and citizens in the co-creation of health data science resources and the delivery of patient benefit and impact. Veli Stroetmann, Director, Empirica Communication & Technology Research, outlined the Digital Health Europe project, aimed at delivering secure access to health data, better data to promote research and personalized health, and digital tools for citizen empowerment and for person-centred care.
Consensus Outcomes:

Coordination is needed to sharing expertise and link genomic and other health data.

The needs for common standards for data quality, security, interoperability, privacy, and ethical guidelines, as well as governance models, have still not been met.

Covid-19 shows the need for fast data transmission to be able to respond quickly.
Closing discussions and conclusions

A final poll of the audience revealed that only just over half of participants (59%) would be fully ready to apply social distance measures in three weeks time. A slightly larger percentage strongly believe that washing hands is an effective measure to tackle COVID-19, while only a third of them strongly believe that wearing a mask is an effective measure.

The closing session confirmed many of the observations made during the course of the conference. Mary Harney, Former Minister of Health and deputy prime minister of Ireland accepted that the EU was caught unprepared by Covid-19, with no integrated plan, and that it was necessary to work more closely together and identify ways to boost the system to be better prepared next time. She suggested that the national sovereignty insistence among member states that has so hindered EU action on health might be weakened by the crisis. Boris Brkljacic, President of the European Society of Radiology, agreed that COVID-19 had shown the limitations of current healthcare systems, with its strained resources, ageing population, and imperfectly coordinated responses throughout Europe. For him, the key takeaways from the crisis the need for enhanced collaboration in healthcare across borders, and utilising the potential of innovation and data for accelerated diagnosis and adequate treatment. Sirpa Pietikainen, a Finnish Member of the European Parliament, agreed that Covid-19 had revealed weaknesses in Europe’s health systems, and had made clear that basic rights should grant all patients equal prevention, screening, early diagnosis, fast and effective treatment, backed by adequate EU resources. Mario Romao of the EMEA Global Public Policy team at Intel characterised EU healthcare as data-rich but insight-poor, and urged building greater mutual trust at the intersection between technology and health, between the fruits of the digital revolution and the policy imperatives to liberate data responsibly. Ultimately, he said, it is about getting the most out of data to help doctors to save lives.

Closing the conference, Denis Horgan underlined that Covid-19 has posed urgent problems but has imparted a new sense of urgency to European health policy. In line with the suggestions made by many session moderators and speakers at the conference, EAPM would now explore how to develop more specific proposals based on the conference’s reflections. It was the moment, he said, for EAPM to mobilise its members to seek translation of urgency into action, and to get member states to adopt permanently the enhanced degree of cooperation they are now struggling to achieve.
Consensus Outcomes:

The coronavirus crisis may promote a new flexibility among national governments states towards European-level action.

The importance of equal access to prevention, screening, early diagnosis, and fast and effective treatment are being demonstrated with unprecedented force.

Mutual trust should be built at the intersection between technology and health.

EAPM has a role in seeking translation of urgency into action on European health care.
Sponsors and Partners

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About EAPM

The European Alliance for Personalised Medicine was launched in March 2012, with the aim of improving patient care by speeding development, delivery and uptake of personalised medicine and earlier diagnostics, through consensus.

EAPM began as a response to the need for a wider understanding of priorities in personalised medicine and a more integrated approach among stakeholders. It continues to fulfil that role, often via regular major events and media interaction.

Our stakeholders 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.

The mix of EAPM members and its broader outreach, provides extensive scientific, clinical, caring and training expertise in personalised medicine and diagnostics, across patient groups, academia, health professionals and industry.

Relevant departments of the European Commission have observer status, as does the EMA, and our engagement with MEPs and Member State health ministries in key policy areas is a crucial part of our ongoing work.

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Next EAPM events

**June 30th, 2020**
Bridging Conference - “Maintaining Public Trust in use of Big Data for health Science”, Brussels, Belgium

**September 18th, 2020**
ESMO Roundtable, Madrid, Spain

**November 17th - 18th, 2020**
German Presidency Conference - “Building a decentralised, data-rich biomarker space to speed better cancer care”, Brussels, Belgium