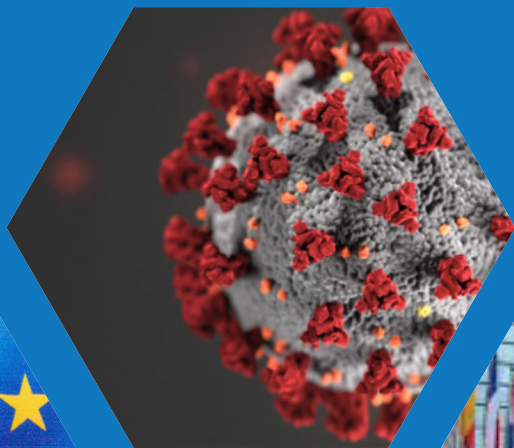


EAPM Presidency Bridging Conference  
between the Croatian Presidency of the  
EU and Germany Presidency of the EU:

# “Maintaining Public Trust in use of Digital Health for Health Science in a COVID 19 and Post COVID 19 World”



**Brussels**  
**30 June 2020**



European Alliance for  
Personalised Medicine

## EAPM Bridging Conference

# “Maintaining Public Trust in use of Digital Health for Health Science in a COVID 19 and Post COVID 19 World”

**Brussels 30 June 2020**

### **Executive Summary**

The battle is far from won to defeat the coronavirus pandemic as it kills hundreds of thousands, infects millions, and constrains so many in lockdowns and social distancing. The challenge can induce dismay, discouragement, even despondency – but the webinar that EAPM held on 30 June offered a very different perspective, visionary, exciting and encouraging. It certainly did not duck the difficult issues, but in facing them head-on, it also highlighted the dynamism and momentum of the science and technology that offers the best hope of vanquishing the immediate enemy, and of constructing a vastly more sophisticated approach to tackling disease and ensuring healthcare.

Participants from the EU institutions, patient organisations, academia and industry and from across a wide range of disciplines and experience recounted not only their current endeavours to provide better protection against disease, but also how they could see a move – with the right degree of trust - towards radical solutions that can improve health for the future.

As with all EAPM meetings, the participation – both among panellists and those who tuned in to the webinar – reflected the diversity of the challenges of personalised medicine and of the multi-stakeholder involvement in meeting those challenges. And the degree of consensus evident on many of the issues discussed will be reflected in other EAPM publications currently in preparation.

The webinar demonstrated the scope and intensity of the work underway – often in the public gaze, but also behind the scenes – in devising and deploying new digital techniques for deepening understanding of human biology.



## The Opportunities

The scale of the potential gains from dramatic progress in healthcare - and improved outcomes for patients - are available if opportunities in early diagnosis are seized. The quest is on for molecular diagnostic tests that can detect unrecognized disease phenotypes at the molecular level, and Christa Cobbaert, the chair of the European Federation of Clinical Chemistry and Laboratory Diagnostics, spelled out how precision cardiology uses these techniques to identify early manifestations of disease before clinical symptoms are detectable, and long before substantial organ damage. This allows molecular changes to be reversed, and the onset of clinically relevant disease to be slowed and even prevented.

She depicted the emergence of digitalised precision medicine as the latest stage in a long progress from mediaeval superstitions about humours to 20th century symptoms observed in biochemistry and organ-based pathophysiology, and on to 21st century molecular biology and the signatures it can capture from multi-omics profiling. She foresaw the expansion of molecular data profiles on millions of individuals where value will reside in defining robust and increasingly accurate causal associations with clinical outcomes, and integrating this new knowledge into clinical workflows.

A similarly inspirational perspective was offered by Pierfranco Conte, Professor of Oncology and Director of the Post Doctoral Fellowship in the Programme in Medical Oncology at the University of Padova. He pointed to the “opportunity not to be missed” in lung cancer through mutational oncology and the use of biomarkers, illuminating a potential path through 300 cancer-associated genes to overcoming the challenge of 860 advanced lung adenocarcinomas. And Andrew Biankin, Regius Chair of Surgery/ Director of Translational Research Centre at the University of Glasgow, recorded the progress with the international Accelerating Research in Genomic Oncology project that aims at “A million patient years of precision oncology knowledge for the world” as it plots the path to precision medicine through 25 programmes in 13 countries with 58,300 donors committed. More than half these projects are planning whole genome/whole transcriptome analysis in clinical sequencing programmes, regulatory clinical trials and discovery research projects, across 20 individual tumour types or subtypes. The project vision is of every patient receiving standardized and comparable molecular testing, and on the basis of robust data able to access new treatments.

Alexandra Geese, one of several MEPs to participate in the webinar, applauded the targeted approach to the prevention, diagnosis and treatment of disease based on an individual’s specific profile.

## The Opportunities

“It starts with the patients, and holds huge potential for improving the health of many of them,” she said approvingly, noting how genome sequencing’s ability to spot a tendency to develop a certain disease down the line has “the potential to significantly alter medicine itself”. The role and potential of molecular diagnostics in opening up new prospects of more precise treatment – not least for rare diseases – is so great that EAPM will shortly be publishing a paper of its own on the subject, which will develop the need for biomarker testing and for updating the EU Recommendation of 2003, a call which was reflected loud and clear during the webinar.

Andrzej Rys, Director for Health Systems, Medical Products and Innovation in the European Commission’s DG SANTE, endorsed the importance of building testing from science. Digitalisation of health is a force whose power has been sharply underlined by the pandemic at every level, from penetrating the nature of the new coronavirus and searching for vaccines and treatments to the most everyday operational level in the wide adoption of telemedicine and digitalisation for knowledge-sharing in difficult circumstances. His view was echoed by Gianmario Candore, Data Scientist at the European Medicines Agency, who pointed out how digital technology is becoming part of the conduct of clinical trial and medicines use, and that adoption of adequately qualified digital technologies can support novel data collection methods while ensuring their regulatory validity. Alastair Kent, formerly Director of Genetic Alliance UK, saw the recent intensive use of telemedicine as inspiration for digitalisation-led improvements to patient services, bringing at the same time additional certainties to industry and wider options to physicians.

Joachim Reischl, VP, Head of Diagnostic Science, Precision Medicine and Biosamples at AstraZeneca, outlined his view of a patient journey reimagined with next generation diagnostics increasing patient benefit with early results delivered through the embrace of data and AI technologies – an approach to personalisation of medicine that had already achieved 39 diagnostic test approvals in the US, the EU, Japan and China for his company in four therapies. Deepak Khanna, Senior Vice President and Regional President for Europe, Middle East, Africa and Canada at MSD Oncology, saw huge opportunity in the shift to virtual consultation and screening and testing via digital tools. And MEP Maria da Graça Carvalho noted the prominence that personalised medicine was attaining in cancer care and rare diseases, with targeted therapies now accounting for nearly half the oncology market, up from just 11 % a decade ago.

## The Opportunities

Patients' associations too perceive the advantages of this evolution: "Healthcare can undoubtedly benefit from the digital and data revolution, with potential impacts at all levels, from diagnosis to treatment to health services organization," said Michele Calabrò of the European Patients' Forum. "The pandemic accelerated the deployment of digital health solutions and proved the importance of health data in managing cross-border health emergencies", he said. Barbara Moss, a patient expert at EMA and a patient ambassador for Bowel Cancer UK, favoured exploiting AI to improve diagnosis and to ease cross-border consultations that assist less well-equipped countries. And Natasha Azzopardi Muscat, Senior Advisor to WHO EUROPE and President of the European Public Health Association, noted how countries are turning more to digital to preserve health services in the face of the COVID 19 challenge.

This growing capacity for exploring digital pathways to advance healthcare has been enhanced by a new degree of collaboration among researchers in the field. Since EAPM's ground-breaking MEGA initiative with its Million European Genome Declaration, 22 European countries have signed up to the EU-endorsed 1M+G successor agreement aimed at creating access to 1 million genomes in the EU by 2022, within a federated framework that would allow secure and authorised cross-border access to genomic and other health data across the EU, supporting research, health care and prevention. Giovanni Tonon, Director of the Center for Omics Sciences and Head of the Functional Genomics of Cancer Unit at IRCCS Ospedale San Raffaele, said that the federated model provided by the initiative had shown a way to overcome data fragmentation, by building trust among institutions.

## Recommendations

- **Develop and deploy molecular diagnostic techniques that can identify early manifestations of disease before clinical symptoms are detectable.**
- **The 2003 EU recommendation on biomarkers should be urgently updated to reflect progress in science.**
- **Adequately qualified digital technologies should be recognised as able to support novel data collection methods while ensuring their regulatory validity.**
- **Exploit AI to improve diagnosis and to ease cross-border consultations that assist less well-equipped countries.**
- **Digitalisation should be used to preserve health services in the face of the COVID 19 challenge.**

## Data

Digitalised healthcare is dependent on data. Authorities, academics and industry are responding to its increasing volume and complexity across multiple settings and devices and to the advances in computational power and in algorithms and methods. HMA-EMA has set up an advisory Big Data Task Force, as Gianmario Candore, Data Scientist at the European Medicines Agency, explained. Biankin's oncology programme makes global data-sharing central to permit learnings from each patient. And Michael Zaiac, Head of Medical Affairs Oncology Region Europe at Novartis, reported how industry was aiming to shift to shared digital platforms utilizing pseudonomized data from electronic health records.

For patients too, access to data can empower them, permitting self-management, shared decision-making, participative care processes, improving quality of life by integration into person-centred "joined up" care, according to Calabrò. And where data can help advance health research and ultimately benefit society, patients are generally comfortable and willing to share, he said. Another patient representative, Natacha Bolanos, Regional Manager Europe for Lymphoma Coalition and a coordinator of the Harmony Alliance T-cell Lymphoma Consortium, shared the view but argued: "We must learn to better use the data we have."

The COVID 19 experience has made the importance of data collection even more evident. For Jan Korbelt, Group Leader and Senior Scientist at EMBL, COVID 19 has imparted a new sense of urgency and motivation. Data transfer "is something we've been working towards for some time," he said, and now "we are heavily engaged with other countries in rapid data exchange on the new coronavirus." COVID 19 will persist as a driver to the process, he added, which will help preparations for the future as well as recovery from the pandemic.

Azzopardi says that COVID 19 "has strengthened our health data systems". MEP Sirpa Pietikainen spoke for many when she said it was essential to move towards harmonisation of data and standardisation of infrastructure. But a nuance was expressed by Stanimir Hasardzhiev, Chair of the Bulgarian National Patients' Organisation: the discussions of the value of data are complicated by each individual patient's approach, and account must be taken of their right to use their data.

## Data

### Recommendations

- **It is vital that all stakeholders learn to make the best use of existing data, and cooperate in creating systems that continually develop new techniques for obtaining and exploiting data.**
- **Authorities, academics and industry should respond more fully to the increasing volume and complexity of health data.**
- **Global data-sharing should become central to permit learnings from each patient.**
- **Data should be used fully to empower patients, permitting self-management, shared decision-making, participative care processes, and improving quality of life by integration into person-centred “joined up” care.**
- **A move towards harmonisation of data and standardisation of infrastructure is essential.**

## Trust

Hasardzhiev's remark touched on the issue of trust – in this case, patients' trust in the reliability of data systems and data users to protect privacy and rights as digitalisation moves ahead. Other trust issues too are at the heart of the debate of digitalisation. Rys added to the list with reference to cybersecurity of data, and urged fuller explanation to patients of the aims of digitalisation, so they understand what is to happen to their information. The pandemic has helped to display the merits of tele-health in limiting physical contact, permitting remote diagnosis, and triaging patients – and slowing transmission, and Moss highlighted the advantages of avoiding unnecessary hospital visits, and suggested that COVID 19 may help in teaching trust, and in encouraging an openness to new treatments and methods.

But Rys suggested that new types of bonds may need to be formed between doctor and patient to maintain trust when they are in contact only remotely rather than face to face. Candore raised the issue of trust by authorities in new forms of data – particularly the acceptability of remotely-acquired data, which demands an understanding of their provenance, quality and validation. Astrid Vicente, Coordinator of the Department of Health Promotion and Prevention of Non-communicable Diseases, and a Principal Investigator at Portugal's Instituto Nacional de Saude Doutor Ricardo Jorge, who is also the Vice-chair of ICPeMed, underlined the need to gain the trust of policy makers to promote implementation of personalised medicine in healthcare systems. And Carmen Laplaza Santos, Deputy Head of Unit Health Innovations in the European Commission's Directorate-General for Research and Innovation, said trust is not just a matter of confidence in technology and security about privacy: it also requires action to counter disinformation that can erode trust, and this requires educating people –stakeholders and institutions - on where to find reliable information.

Calabrò too spoke of tackling confidence in e-health solutions not just among patients but among healthcare professionals, including in meeting concerns over the transparency – and accuracy – of tracing apps developed for the pandemic. MEP Nicolas Gonzalez Casares lamented lack of established trust and tools in data sharing, which had resulted in the loss of some opportunities for advancing digitalisation. A further issue highlighted was the conspicuous case of the recently published – and then withdrawn - studies on hydroxychloroquine, based on data later revealed to be questionable, which had challenged credibility of established systems.

## Trust

Patients believe, according to EFP surveys of its members, that health systems should learn from the COVID 19 crisis in positive adoption of technology - “There’s now the chance to shape the future of health data and digital health in Europe”, by “involving patients at all level, from innovation development to policy-making”. A broader area where trust is at a premium is how far authorities retain their credibility with members of the public - who have, for instance, shown remarkable trust in complying with imposed restrictions during the first half of 2020. Risks of corroding public trust arise from imprecision over the rules for restrictions, or inconsistent provision of figures on rates of infection or mortality or testing. WHO sees the post-COVID 19 phase as an opportunity for vertical and horizontal digitisation of health services, Azzopardi reported, and she insisted on coalition building to nurture public trust, “because it is the public that will drive digitalisation and the transformation of health systems.”

## Recommendations

- **Arrangement must be made for patients to trust in the reliability of data systems and data users to protect privacy and rights as digitalisation moves ahead.**
- **New types of bonds may need to be formed between doctor and patient to maintain trust in circumstances - such as telemedicine - where contact is remote rather than face to face.**
- **New relationships may need to be formed between sponsors and authorities to ensure trust in new forms of data - particularly the acceptability of remotely-acquired data.**
- **Policy makers should be open to new ways of learning to trust so as to permit the implementation of personalised medicine in healthcare systems.**
- **Action is required to counter disinformation that can erode trust, by educating stakeholders.**
- **Confidence needs to be built in e-health solutions not just among patients but among healthcare professionals.**
- **Authorities need to ensure they retain their credibility with members of the public by delivering consistently clear and candid advice and data on health challenges.**

## Making it happen

Digital transformation of health systems is an explicit element in the job description of Laplaza Santos, and in her very candid view it is urgently needed, as health systems currently suffer from fragmentation, and are slow to adapt to change and to respond to disruption. Calabrò agreed: “The road to fully exploit the benefits of digital health, in particular data and AI, is still extremely fragmented and not yet developed with patients’ views at the centre.” He itemised deficiencies in interoperability, common health data definitions and frameworks, and digital health accessibility, and cited “ad-hoc approaches to innovation rather than systematic evaluation and implementation”. From the perspective of diagnostic development, Cobbaert highlighted the failings in linking health systems and research, which leads to continuing use of tests that are “almost blind for specific molecular defects”, while only about 100 disease-associated biomarkers are routinely deployed in the clinic, with most of the thousands so far discovered not validated or used. Carvalho noted with disapproval the lack of coordination between development and regulatory pathways for diagnostics and medicines, and Bernarda Zamora, Senior Economist at the UK Office of Health Economics, pointed to the barriers in reimbursement systems that are unadapted to advanced diagnostics. There was wide support for better coordination and synchronisation, and for a breaking down of the current silos that limit thinking.

But, as Laplaza went on to explain, a search for greater coherence is underway. Twelve member states are already cooperating in a new programme to promote innovations in health systems and their organisation, constructing a platform “for transition to high-quality, people-centred and resilient health and care services accessible at affordable prices to all European citizens through a partnership approach.”

This is more than a straw in the wind. Europe and its approach to health is in a time of rapid change, and there was plenty of evidence of it before the pandemic raised new questions over EU health policy. An EU digital health strategy was already in preparation when the new Commission took office in late 2019 and set new high targets for health. Martin Dorazil, Deputy Head of Unit for European Reference Networks and Digital Health in the European Commission outlined the health priorities in the EU’s Digital Single Market Strategy – which included better access for citizens to their health data, connecting and sharing health data for research, faster diagnosis and better healthcare outcomes, and expanding digital services for person-centred care. He also spelled out the aims of the European Health Data Space the new Commission has embraced, to mobilise health data for better healthcare, better policy making and better research and innovation.

## Making it happen

Alongside, a large-scale 'Beating Cancer Plan' was launched in February, and a parallel Cancer Mission has been taking shape since last year. The EU workplan for 2020, agreed in January, announced a review of the many complex issues of medicines in a Pharma Strategy for the end of 2020. As part of the EU's emergency recovery plan from COVID 19, a new health programme was announced in May with an unprecedented €9bn budget - and as Rys pointed out, this contains a large component on digitalisation. At the same time, the EU has put direct funding into drug and vaccine research projects linked to COVID 19, and in June it agreed a new plan to support vaccine development and manufacture with advance purchase agreements and a budget of €2.7 bn. As Rys put it, "Things moved fast with COVID 19, with big changes in just weeks, and new systems almost overnight" - with what he described as collective efforts driven by many participants sharing the direction of the project. There is also a growing chorus urging greater powers to the EU for health, as exemplified by MEP Sirpa Pietikainen's insistence on the importance of the EU exercising its competence to the fullest to take a more active role - a call echoed by networks of scientists, practitioners, patients organisations.

All this will have direct or indirect consequences across the range of European healthcare policy and practice. One of the beneficiaries could be the treatment of rare diseases, highlighted during the webinar, and which should find its echo in the ongoing discussions on adaptations of the Orphan Regulation (a subject on which an EAPM publication has recently synthesised the needs and hopes).

But there was also recognition in the webinar that injudicious responses could have downsides for health. Calabrò pointed to pandemic's exacerbation of health systems' existing lack of capacity and preparedness to provide timely access to diagnosis and care. Azzopardi counselled against losing the effectiveness of health systems if COVID 19 shifted the focus too far, or deterred patients from seeking routine care by inspiring fears of infection. Warnings on the negative impact on cancer care and cancer patients came from many participants. Patients like Moss said treatments, screening and check-ups had virtually stopped, and Bolanos pointed out that "cancer is not going to wait for COVID 19 to pass." Industry figures such as Khanna noted that skin cancer diagnosis had dropped by 60% during the pandemic. And Tit Albrecht of the National Institute of Public Health of Slovenia, noting the competition for attention as COVID 19 cut into cancer care, spoke of waiting lists with a "backlog of colorectal patients who just couldn't wait any longer".

## Making it happen

Remedies advanced – by among others, Panos Kanavos, Associate Professor of International Health Policy in the Department of Health Policy at the London School of Economics - included more rational allocation of resources, to bring more efficiencies in health care, with early diagnosis and better use of technology making healthcare systems more cost efficient too. Solutions would require profound reviews of current ways of thinking. More to bring more efficiencies in health care, with early diagnosis and better use of technology making healthcare systems more cost efficient too. Solutions would require profound reviews of current ways of thinking. More openness to financing options for healthcare products and services should explore new or emerging payment models. Bringing products to the market would have to be streamlined to avoid delays from lengthy reimbursement negotiations. And healthcare systems should be shifted to demand-led rather than the current supply-driven model, Kanavos suggested. There was also general recognition that developing health literacy was an essential ingredient – not merely for citizens, but for healthcare professionals too.

But improvements brought about by the COVID 19 experience were also applauded. Korbel said he had been impressed by the scientific community's sharing and collaboration, and Biankin noted that many forced accelerations and collaborations should be maintained post-COVID 19. Consensus was strong on the merits of health system transformation, better integration of digitalisation in public health, connected infrastructures and platforms, and wider standardisation, interoperability and quality controls. Azzopardi and Biankin both insisted on need for interoperability and alignment, on being able to break down silos that currently impede the aggregation of data from different sources. Benjamin Horbach, Health Systems Strategy Leader at Roche said that “our multistakeholder work to embed personalised healthcare into Europe's healthcare systems is gathering pace as evidenced by the work undertaken by cross-stakeholder collaboration. There is still the need to build a better, healthier world for all citizens and continue to accelerate a robust and sustainable personalized healthcare system in the future. Better uptake of molecular diagnostics to support earlier diagnosis and the use of data governance frameworks such as the European Health Data Space are crucial steps that go in the right direction”.

Overall, an optimistic picture of aspiration emerged from the webinar, with digitalisation as a way to bridge the gaps and make healthcare more participatory, with wider and more frequent dialogue, more continuous monitoring and expert interpretation with high tech aids, and a health system that evolved from collaboration to co-creation. The webinar was a salutary reminder of the energy and inventiveness of Europe, scientifically, industrially, socially and politically, in exploiting the possibilities of digitalisation in healthcare... and a clear demonstration of how developing all that potential depends, ultimately, on trust.

## Making it happen

A broader area where trust is at a premium is how far authorities retain their credibility with members of the public – who have, for instance, shown remarkable trust in complying with imposed restrictions during the first half of 2020. Risks of corroding public trust arise from imprecision over the rules for restrictions, or inconsistent provision of figures on rates of infection or mortality or testing. WHO sees the post-COVID 19 phase as an opportunity for vertical and horizontal digitisation of health services, Azzopardi reported, and she insisted on coalition building to nurture public trust, “because it is the public that will drive digitalisation and the transformation of health systems.”

## Consensus Recommendations as outcome of the Presidency Bridging conference, June 30th

- **Fragmentation in health systems must be overcome, and patients' views put at the centre.**
- **Improvements are needed in data interoperability, common health data definitions and frameworks, and digital health accessibility.**
- **Ad-hoc approaches to innovation must give way to systematic evaluation and implementation.**
- **Policy should be directed at linking health systems and research more closely to ensure take-up of valuable and validated innovations.**
- **Coordination is needed between development and regulatory pathways for diagnostics and medicines.**
- **Reimbursement systems should be better adapted to advanced diagnostics.**
- **EU powers for coordinating health should be exploited to the full, and consideration given to possible extension where appropriate.**
- **All efforts should be made to overcome health systems' existing lack of capacity and preparedness to provide timely access to diagnosis and care.**
- **More rational allocation of resources, early diagnosis and better use of technology could bring more efficiencies in health care.**
- **More openness is needed to explore new or emerging payment models and other financing options for healthcare products and services.**

## Making it happen

- **Healthcare systems should be shifted to demand-led rather than the current supply-driven model.**
- **Health literacy should be developed for citizens and for healthcare professionals.**
- **Health systems should overcome silos that currently impede data interoperability and alignment and prevent the aggregation of data from different sources.**
- **Digitalisation should be recognised as a way to bridge the gaps in healthcare and to make it more participatory.**

## Sponsors and Partners



## 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.

### **Contact:**

**Denis Horgan**

EAPM Executive Director

Avenue de l'Armee/Legerlaan 10, 1040 Brussels

**+ 32 4725 35 104**

**[denishorgan@euapm.eu](mailto:denishorgan@euapm.eu)**

**[www.euapm.eu](http://www.euapm.eu)**

## Next EAPM events

### **14 July, 2020:**

EAPM Global Conference “Forward Together - Where we are now and the necessary next steps for a resilient healthcare System”  
- effective ways of investing in healthcare in a COVID 19 and Post COVID 19 World

### **18 September, 2020:**

ESMO High Level Roundtable ‘Seeking innovation solutions at for cancer patients and citizens’

### **13-14 October, 2020:**

German Presidency Conference: “Building a decentralised, data-rich biomarker space to speed better care and quality of life for citizens and patients”

### **November 2020:**

2nd EAPM Global Conference: “Providing a global forum to ensure Public Trust in empowering Digital Data for health Science in a Covid

