



European Alliance for Personalised Medicine

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Alliance goes 'MEGA' on EU genomes initiative

Welcome to EAPM's October newsletter. Busy times lie ahead, as ever, with our ongoing development of the MEGA project, the general assembly of HARMONY, a landmark personalised medicine conference taking place in the Balkans later in the month and, of course, our own Congress in Belfast. Meanwhile, there was the...

Juncker speech

Recently, European Commission President Jean-Claude Juncker gave his now annual 'State of the Union' address at the Parliament in Strasbourg, but observers in the field were surprised to hear little mention of healthcare.

In one small section Juncker did, however, state that it is unacceptable to still have children dying of measles in Romania or Italy. He added that these "avoidable deaths must not occur in Europe", but on healthcare in general he was silent, with the word 'patient' failing to appear anywhere in the speech.

As his speech showed, Juncker is basically advocating more federalism now that one of the EU's regular and most vociferous opponents, the UK, is waving goodbye in 2019. He seems keen to grasp the nettle and push for more integration in various key areas. But not in health, it seems, and given that this area will affect every single EU citizen at one or another stage in their lives, this is a worry.

His comment about taking a "very critical look at all policy areas to make sure we are only acting where the EU adds value," has had healthcare watchers wondering whether that means a Europe that will be less involved in transnational health issues, rather than more involved, as many want.

Stakeholders will be watching closely.

MEGA project

The Million European Genomes Alliance (MEGA) initiative is moving forward after EAPM's engagement with the European Commission and certain Member States.

Better use of our increasing understanding of the genome is recognised as being one of the main determinants of future improvement in healthcare as part of personalised medicine and is already being increasingly deployed in routine clinical practice.

In the pipeline

- **11 Oct: World Sight Day workshop, European Parliament, Brussels**
- **23 Oct: GDPR roundtable**
- **23-24 Oct: HARMONY general assembly**
- **26-27 October: Balkan personalised medicine conference, Sofia**
- **27-30 Nov: EAPM Congress, Belfast**

Sequencing of all the genetic material of an individual, whole genome sequencing, is becoming an affordable and achievable test for clinical use and creates a powerful resource for research.

This MEGA project will take into account that every country has bigger or fewer resources, but the stunning concept would ideally see a linking together of the efforts in order to reach the one million figure.

A number of genome sequencing initiatives at scale in the last few years to try and capitalise on this potential. Within the EU the UK has led the way with the 100,000 Genomes Project. MEGA would take this much further.

Moreover, such a project would be a realisation of the aims expressed in Article 35 of the Luxembourg EU Presidency's Council Conclusions on personalised medicine to "encourage dialogue with Member States' authorities and stakeholders to facilitate step-by-step implementation of the public health genomics approach both at European Union and national level...and facilitate ongoing initiatives".

In the EU, of course, healthcare is a national competence, but we have floated the idea that each Member State (or at least a 'coalition of the willing') should develop a genome project proportionate to their populations.



Consultation responses

EAPM has responded to the consultation document '*Transformation of Health and Care in the Digital Single Market*' and has made the following observations, among others:

With rising healthcare costs and individual health systems being increasingly challenged, Big Data and specifically genomics has the potential to impact the health of all of us and provide diagnostic, economic and efficiency benefits, ensuring that patients receive the right information and the right treatment at the right time.

Meanwhile, better use of our increasing understanding of the genome is recognised as being one of the main determinants of future improvement in healthcare as part of personalised medicine and is already being increasingly deployed in routine clinical practice.

Sequencing of the all the genetic material of an individual, whole genome sequencing, is becoming an affordable and achievable test for clinical use and creates a powerful resource for research.

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, the treatment of rare diseases and more.

Two-thirds of Europeans think that the most recent digital technologies have a positive impact on society, the economy and their own lives.

There is a need for policy measures that will "promote digital innovation in improving people's health, and address systemic challenges to healthcare systems".

Issues arising include legislation on data protection, patient rights and electronic identification and it is indeed important to develop a "European health record format that citizens can access from anywhere in the EU" and render it "more seamless".

The advancement of research; disease prevention and personalised healthcare can now become a reality, even across borders, although cross-border healthcare is as yet not optimal

- hence the need for, as the Commission puts it, "large-scale implementation of interoperable digital services that support health system reforms and capacity-building towards more patient-centered and integrated care."

EAPM recognises the need for a multi-location digital infrastructure and data exchange platform, which will be especially (but not exclusively) useful when it comes to rare diseases.

Consultation remains open until 12 October and we would encourage all relevant stakeholders and partners to have their say [here](#)

Data protection

The European Commission has organised a roundtable for 23 October to talk about implementing the General Data Protection Regulation at national level.

EAPM is currently focussing on the problems inherent in sharing vital medical data, as there are issues with gathering, storing and disseminating the intelligence, as well as obvious ethical ones covering privacy of the individual.

Data for medical research often hits bottle-necks because of silo mentalities, interoperability problems in the necessary IT structures, confidentially concerns among pharmaceutical companies and legal minefields over individual rights to control information.

With the emergence of personalised medicine, new technologies (notably genetic-based, imaging-based, and immuno-therapeutic drugs) are allowing for the sort of specialised and targeted treatment that is the ultimate goal of former US President Obama's Precision Medicine Initiative, and EAPM's MEGA plan, which is outlined briefly an earlier section of this newsletter.

At the Commission roundtable, we aim to:

- Help to create a consistent regulatory environment that provides certainty and ensures patient safety in the area of CTD, DPR, IVD and so on. This will facilitate innovation. As we know, the EU has world class research but, often, the benefits are



GOOD SCIENCE
BETTER MEDICINE
BEST PRACTICE

European Society for Medical Oncology

taking longer to get to citizens than should be the case.

- Reassure citizens and politicians regarding medical data. The EU has comparative advantages compared to other regions in the world as it has strong data protection rules so citizens/companies can be assured that the data is safe.

- Push for a framework that allows for collaboration between regions in the EU in order that they can access data for research purposes, thus facilitating for innovation. Trust is a vital component, here.

HARMONY general assembly

The HARMONY GA takes place on 23-24 October at Bayer in Berlin. The meeting's agenda has a strong scientific focus and will emphasise the seven HM Pillars. The event will allow all HARMONY partners and associated members to come together to discuss and reach agreement on existing and forthcoming bench-to-bedside projects and more.

The event will start with what the organisers call a session aimed at building a bridge between the diverse perspectives on outcomes arising from stakeholder groups.

Sofia PM conference

EAPM will be present in Bulgaria toward the end of October to take part in the first PM conference to be held in the Balkans.

Taking place from 26-27 October, the objective of the two-day event is to outline the stage of development, challenges for implementation and future trends in personalised medicine in the Balkan region.

The conference will focus on the presentation of scientific projects, clinical, diagnostic and organisational methods, integrated approaches, real-world-evidence, real-world data and experience in the field of precision and personalised medicine.

EAPM's executive director, Denis Horgan, will speak at the conference.

The Alliance at ESMO

The Alliance held a key roundtable at the ESMO Congress in Madrid (10 September).

The high-level discussions under the banner 'Personalised Medicine: Translational Continuing Education Initiative' held in the Spanish capital, represented the fifth such roundtable conducted by EAPM at the Congress.

This type of interaction is one key aspect of EAPM's stated goals - to engage with the medical community whenever possible, and at every level.

Attendees at the roundtable included patients, public health experts, economists, industry representatives from ICT and pharmaceutical companies, and other specialists from across multiple disciplines.

EAPM's multi-stakeholder, high-diversity meeting took into account the fact that new discoveries - generated from a deeper understanding of the human genome - are driving a paradigm shift in medicine from a one-size-fits-all approach to one which is personalised and targeted to the individual.

Further topics discussed in depth were incentives and screening. Siemens Healthcare put forward a presentation on the role of screening, while Maarten Izjerman, Dean of Health and Biomedical Technology, faculty Science and Technology at the University of Twente, spoke about the issues of economics and rational use of resources.

Patients were represented, meanwhile, by Natasha Bolanos, of the Spanish Group for Cancer Patients (GEPA).

Other matters arising at the all-day roundtable took into account the ongoing developments in the field of personalised medicine, such as DNA profiling, concepts of 'value' and biomarkers and, because of the diversity of the disciplines of the delegates attending, the meeting constituted a bridge between new developments and those that will implement them, as well as the patients who will eventually benefit.



EAPM executive director Denis Horgan said after the event: "As ever, it's extremely important to hold a roundtable at the ESMO Congress. It's one way that we can reach out to the many experts in cancer and personalised medicine, as well as hearing their's and patients' views on all of the issues, including ongoing education for healthcare professionals and the implementation of innovation."

World Sight Day

MEPs Marian Harkin and Cristian Silviu Buşoi will host a eyesight workshop in the Brussels European Parliament ahead of World Sight Day (12 October). The workshop is on the 11th.

This year, World Sight Day will be held under the banner '*Make Vision Count*'. It is an annual day of awareness to focus global attention on blindness, visual impairment and rehabilitation of the visually impaired, and was first held in 1998.

A White Paper on blindness (with involvement from EAPM) is set to be launched at the same time.

Key decision makers, policymakers, government officials, patients, partners/donors and the wider health community participate in World Sight Day, with annual events taking place all over the globe.

The White Paper will highlight that eye disease and its prevention is a major issue in Europe today and will only become bigger as the 500-million-plus population ages (and the incidence of, for example, diabetes grows).

There are some 39 million blind people in the world, but 80 per cent of blindness can be cured or prevented.

Belfast Congress

EAPM is now focusing hard on the First Annual European Personalised Medicine Congress, to be held across four days (27-30 November) in Belfast, Northern Ireland.

The majority of speakers have now been confirmed and a substantial number of scientific abstracts have been received with a wide range of stakeholders represented.

Early Bird registration closes in a few days, so now is the time to book your place for what will be a one-stop-shop for discussion about the fast-moving world of personalised medicine. The Congress will act as a bridge and a 'point of excellence', bringing researchers, scientists, policy makers, patients, healthcare professions together with a view to advancing conclusions regarding necessary actions, reached by consensus, to politicians at regional, Member State and EU level.

The Congress website, the abstracts portal, and online registration are all available and the current programme can also be viewed. (See links below.)

Key areas that the Congress will include:

- **Patients** - Modern-day patients are better informed than ever before and are demanding to share in co-decision making



about issues affecting their treatments. They are also hugely in favour of being able to share their own private health data (under strict ethical and privacy provisions) for the benefit of fellow patients and future generations.

- **Education & Training** - Healthcare professionals (HCPs) are falling behind with front-line knowledge as developments in personalised medicine move swiftly. Europe must put programmes in place to bring, and keep, these HCPs up to speed.

- **Regulation** - Proponents of personalised medicine believe that much legislation governing aspects of healthcare is out-of-date and not fit for purpose in these fast-changing times. Regulations and directives must be brought up to modern levels through a consensus of experts and key actors, including patients.

- **Research & Development** - EAPM has always promoted state-of-the-art research, and this will be a focus of the Belfast Congress which will be held at The Waterfront venue (above).

Useful Congress links

[Congress Programme](#)

[About the Congress](#)

[Session formats](#)

[Sessions styles](#)



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About EAPM

The European Alliance for Personalised Medicine (EAPM) , launched in March 2012, brings together European healthcare experts and patient advocates involved with major chronic diseases. The aim is to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics, through consensus.

As the European discussion on personalised medicine gathers pace. EAPM is a response to the need for wider understanding of priorities and a more integrated approach among distinct lay and professional stakeholders.

The mix of EAPM members 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. EAPM is funded by its members.

**Contact: Denis Horgan
EAPM Executive Director
Avenue de l'Armee/Legerlaan 10, 1040 Brussels
Tel: + 32 4725 35 104
Website: www.euapm.eu**