



# European Alliance for Personalised Medicine

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## Alliance sets its stall out for a busy 2016

Hello, and welcome to the first EAPM newsletter of 2016. The Alliance hopes that all members and associates enjoyed the holiday period and are back in the swing of things as we move into February.

### Data protection and Council Conclusions

Details of the new General Data Protection Regulation were made public at the end of last year and the Alliance contributed a great deal to a piece of legislation that saw around 4,000 amendments to the original draft as it developed and changed.

Now the 'Trilogue' of European Parliament, Council and Commission have reached agreement and its impact in the arena of health, especially health research, will be immense.

Over three years, EAPM, alongside key members and partners including ESMO, EORTC, EPF, EHA, EAU, Science Europe and Wellcome Trust, tabled 10 key legislative amendments to Parliament through the LIBE, ITRE and ENVI Committees, all of which were supported in plenary.

This was made possible as the Alliance held a central role in bringing major stakeholders together to present concerns from platforms representing patients, researchers, scientists, healthcare professionals and more.

Down the years, the Alliance has organised many stakeholder meetings on Big Data and data protection, including one in the European Parliament in collaboration with Wellcome Trust, FEAM and Science Europe.

This was designed to convey key messages about the need for data to be shared in a way that does not block vital research.

This was followed by numerous meetings with MEPs on critical points, augmented by a document for all new Members joining the latest legislature that highlighted issues relating to data protection, clinical trials and research.

That document was strengthened by an EAPM-organised roundtable with new Parliamentarians to explain the Alliance position and garner their support. The roundtable was backed up by numerous briefing documents prepared for EAPM members.

Meanwhile, Big Data and the data protection regulation have, of course, always played a part of EAPM's Annual Conference.

### In the pipeline

- **15 February: Roundtable meeting on clinical trials, Brussels**
- **2-7 March: SMART Outreach meetings in Poland and Italy**
- **4 April: EAPM to host meeting focusing specifically on issues surrounding genomics and its future role**
- **5-6 April: 4th Annual Conference, Brussels**
- **4-8 July: Summer school for HCPs, Strasbourg**

Several of the key points that the Alliance raised across the course of the regulation being formulated can be seen below.

Paragraph 26 of the regulation calls for 'a number, symbol or particular assigned to an individual to uniquely identify the individual for health purposes,' and this will be vital to ensure that valuable medical data can be collected, stored and shared. This came after many strong calls to strike a sensible balance between protecting the patient and freeing up vital data to progress research and personalised medicine during this generation and those that will follow.

Paragraph 42b, meanwhile, includes safeguards acknowledging that 'The processing of special categories of personal data may be necessary for reasons of public interest in the areas of public health without consent of the data subject. But 'such processing of personal data concerning health for reasons of public interest should not result in personal data being processed for other purposes by third parties such as employers, insurance and banking companies'.

EAPM campaigning also resulted in influential input into many other paragraphs, such as Paragraph 88, which concludes that 'For scientific and historical research purposes or statistical purposes, the legitimate expectations of society for an increase of knowledge should be taken into consideration.'

On top of this, the Alliance played a key role in helping to shape the landmark Luxembourg Presidency Council



Conclusions on personalised medicine at the end of last year - after six months of working hand-in-hand with the Grand Duchy, and specifically the department run by Health Minister Lydia Mutsch.

Part of the rotating presidency's job is to prepare Council Conclusions on various topics to be delivered at the end of its term in office – in Luxembourg's case, last December. Typically, a Council Conclusion invites member states and/or another EU institution (for example, the Commission) to take action on a specific topic.

These conclusions are often adopted in areas where the EU has the competency to support, coordinate and supplement, for example in the arena of health, and those on personalised medicine came on the back of a high-level conference held in July 2015 and several subsequent discussions.

The conference, entitled 'Making Access to Personalised Medicine a Reality for Patients', addressed obstacles to the integration of personalised medicine into EU health-care systems, identified best practices and their added value and outlined the potential benefits of personalised medicine for public health and its impact on policy-making in the EU.

The high-level meeting also underlined the need to define a patient-centred approach to personalised medicine at EU level, involving decision-makers and regulators in the area of public health, as well as a comprehensive approach integrating the different phases along the life cycle of personalised medicine products in such a way as to facilitate its integration into clinical practice.

The Alliance played a major part in the Luxembourg Presidency's summer conference, has given coordinated input into many policy matters ranging from data protection, to IVD and clinical trial regulations.

The collaboration was a great success and you can see various stakeholder reactions to the conclusions on video, [here](#).

## 4th annual conference

The theme of EAPM's fourth annual conference, on 5-6 April 2016, will be: "Taking Stock: Where we are now and the necessary next steps."

Personalised medicine has never been more in the public eye than it is now, especially given US President Barack Obama's initiative, and the conference aims to reflect this.

The Americans are moving quickly and have come to some obvious conclusions including that health equals wealth and that investment in research and innovation, alongside laws and rules that are fit-for-purpose and reflect the swiftly changing world of medicine, are vital.

Europe needs to grasp these points at every level – not just the vision of an EU that creates a competitive environment that attracts investment, but also for the benefit of the millions of potential patients spread across 28 Member States.

At the conference in Brussel's prestigious Bibliothéque Solvay (pictured above), high-level speakers and attendees will come from a wide range of stakeholder groups including patients, healthcare professionals, academics, industry representatives, politicians and legislators, the media and more.

As mentioned above, the Luxembourg Presidency has published its [Council Conclusions](#). These (and subsequent actions) will feature heavily in the Alliance's conference.

EAPM will examine its recommendations as part of the 'Taking Stock' topic base. And, as in previous editions, the conference will be held across one-and-a-half days, and the aim is to see real and concrete recommendations emerge.

It is necessary to formulate a patient-centred strategy involving EU decision makers and regulators in the arena of public health, to enable the EU and Member States to contribute to integrating personalised medicine into clinical practice while enabling much-greater access for patients.

In order to provide a clear focus and to devote sufficient space



to analysis, discussions during the conference will concentrate on how:

- to assess and address obstacles to the integration of personalised medicine into Europe's healthcare systems
- to identify best practices and their added value
- to outline the potential benefits of personalised medicine on public health and its impact on policymaking in the EU

EAPM's various Working Groups will analyse the Luxembourg Council Conclusions on personalised medicine and help to realise the proposals within them. This will involve developing position statements on key issues via roundtable discussions and following these up with Member States and the European Commission, among others.

Attendees will be drawn from key stakeholders whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum.

Participants already confirmed include public health decision makers, health ministers, representatives from the Commission, 12 Members of the European Parliament, patient organisations, and umbrella organisations representing interest groups and associations actively engaged in the field of personalised medicine.

Each session will comprise panel discussions, Q&A sessions and roundtable working groups to allow the best possible involvement of all participants and reach concrete conclusions and solutions.

As a starter to the proceeding, the previous day (4 April) will see EAPM host a separate meeting focusing specifically on the issues surrounding genomics and its future role.

We look forward to welcoming you in April. Registration opens next week.

## **Molecular diagnostics - access and reimbursement**

Coming up in April will be a special issue of *Public Health Genomics* looking into equitable access to molecular diagnostics as well as the policy and health technology assessment implications.

A workshop will also be organised to present and underline these issues to politicians.

Next General Sequencing (NGS) is very quickly becoming a significant technology not just in research but also in clinical diagnostics. The challenge for the next several years is working with the many stakeholders across the globe that will be instrumental in determining whether NGS can be a successful technology in the diagnostic space.

This will be determined at least in part by how countries approach regulation of NGS both in the short and long term, whether existing reimbursement policies will work for NGS or whether new policies will need to be created and how technology assessments will be performed in the light of the enormous amount of data that can be generated with this technology.

Molecular diagnostics can offer important benefits to patients, healthcare professionals and healthcare systems and they are a key factor in the development towards personalised medicine.

However, despite their promises, few molecular diagnostics are integrated into clinical practice (especially in Europe) and access to these technologies remains inequitable across countries and sometimes even within individual countries.

If the research and the regulatory environment have proven to be more challenging than expected, reimbursement and value assessment remains the main hurdle to providing equitable access to patients.

Unclear or non-existent reimbursement pathways, together with a lack of clear evidence requirements, have led to significant delays in the assessment of those technologies in some countries.





Among other topics, the special issue article will attempt to consider the situation from different perspectives (patients, healthcare payers, healthcare professionals and manufacturers). More details to follow.

## Big data

EAPM will soon hold an internal meeting focusing on how to realise Luxembourg Council Conclusions on this important topic. The Alliance has identified genomics as a key area in this respect.

An upcoming campaign initiative will be driven by EAPM and its members with the aim of engaging and informing EU and Member State policy makers in order to shape the landscape for the successful implementation of genomics and related technologies in the healthcare arena. Such action will go a long way to realising the vast potential of personalised medicine.

Understanding of genomics has increased substantially since the year 2000, by which point the majority of the genome had been sequenced as part of the Human Genome Project. Research over the past 15 years has greatly improved our understanding of the genome's implications for health. These advances have been matched by a revolution in technology, including the development of Next Generation Sequencing (NGS) whose every reducing costs are making this technology more available for clinical applicability.

Clinically and scientifically, there is a compelling case to be made for the widespread introduction of NGS technologies into, for example, clinical trial delivery and modern pathology practice, such that the results of these innovative technologies can be passed directly to patients.

Genomic medicine can also contribute to enhanced patient care from both cost/benefit (more accurate patient stratification for treatment) and patient quality-of-life (reducing the likelihood of treatment toxicity) perspectives.

The application of healthcare genomics provides significant potential for improving the health of the EU's 500 million citizens across 28 Member States.

## Outreach events

EAPM's latest SMART Outreach meetings are taking shape to set up an Alliance presence nationally.

The Alliance's June 2015 EAPM conference introduced the 'SMART' concept, which stands for Smaller Member States and Regions Together, and EAPM has been expanding this by taking its message directly to EU countries.

Successful outreach events have already been held in Poland, Austria and Bulgaria and more are planned in 2016 at venues in France, Northern Ireland and Italy, as well as a second event in Poland.

Although Brussels-based – which helps to better engage with the European Commission, EU permanent representations and the European Parliament in the 'Capital of Europe' – EAPM believes it is time to place its feet firmly on the ground in more EU countries, in order to expand its work with the multi-stakeholder groups, and nations, that form its membership.

Meetings are currently being planned for 2 March in Poland, 7 March in Italy, 26 April in Belfast and 4 July in France. Agendas for these meetings will be available in due course on the [EAPM website](#).

## Clinical trials

The Alliance recently had published a series of articles on clinical trials in *Public Health Genomics*.

Under the title: 'Getting Personal: The Future of Medicine and Clinical Trials', these articles are available [here](#).

EAPM has arranged a roundtable meeting on this topic for 15 February in order to prioritise both the challenges and the solutions identified in the articles.



## Interviews

Several 'Taking Stock' stakeholder interviews, which EAPM undertook over the course of the past few months, are available online. These will be regularly added to during the coming weeks.

You can read the currently available interviews, [here](#).

## Summer school for healthcare professionals

From 4-8 July 2016, EAPM will host its first school for the latest generation of healthcare experts. The first classes, to be held in Strasbourg, will focus on doctor/patient communication and will involve young professionals in the age range of 28 to 40.

The faculty will consist of representatives from a cross-section of European medical societies and will feature a combination of lectures during the mornings and role play in the afternoons.

The curriculum will be available this month (February).

## In the news

As ever, EAPM has had several articles published in the media recently. Readers can access these by clicking on the titles below.

[Europe awaits screening assessments for lung cancer](#)

[Drawing conclusions from Council Conclusions](#)

[EU draft health document has stakeholders gathering to respond](#)

[Time to get clinical over much-needed guidelines](#)

## 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.**

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