



European Alliance for Personalised Medicine

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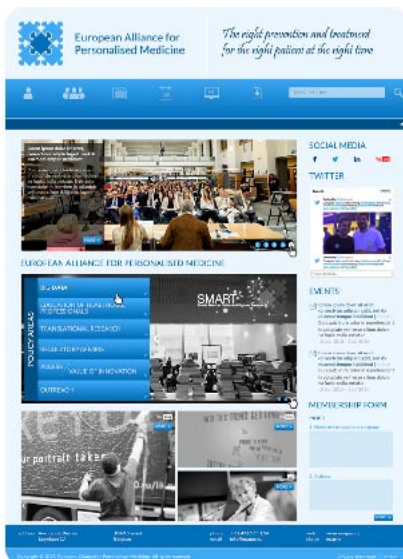
EAPM gears up for busy new season

Warm greetings to all EAPM members and colleagues, and we hope that you have all enjoyed a refreshing break during the summer.

Now, as we reach September, the hard work of realising the potential of personalised medicine begins again in earnest.

Great progress has been made over the past few months - not least during our own annual two-day meeting (June) and a landmark, high-level conference in early July organised by the Luxembourg Presidency of the European Union (with a heavy input from the Alliance - more of that later in this newsletter).

Meanwhile, we invite readers to visit our newly designed website, which launched recently. To take a look, please click [here](#).



Data Taskforce latest

The first meeting to discuss a multi-stakeholder European Taskforce on Health Data will take place on 14 September, and the Alliance is a key player.

Coming up:

- 8 September: Meeting on proposed 2016 Summer School to train HCPs in personalised medicine
- 9 September: Launch of 'SMART Outreach' at The Economic Forum in Krynica, Poland
- 14 September: Meeting of the Data Taskforce to set up a multi-stakeholder group in advance of a proposed European Commission 'Committee of Experts'
- 14 September: Meeting on IVDs: 'An overview of the state of play and consequences for stakeholders'
- 26 September: Clinical Trials roundtable at the ECCO Congress in Vienna, Austria
- 30 September: Second 'SMART Outreach' event. European Health Forum Gastein, Austria

The improved use of health-related data can transform both our healthcare systems and the lives of patients.

However there is also legal uncertainty and a widespread public perception that there are significant risks associated with the sharing of health research.

Access to personal data ultimately depends on public confidence in how it is managed and that this will require sustained and transparent dialogue.

We need a responsive system of regulation that offers high levels of protection for individuals and high-quality data access for researchers and healthcare providers. It is evident that data protection is a fundamental and growing issue.

Sustained dialogue between stakeholders is needed to ensure that we make the right choices in Europe and build on the framework that will be provided by the new Data Protection Regulation.

The Commission has concluded that the EU needs a more comprehensive and coherent policy on the fundamental right to personal data protection.



SMART

Smaller Member States And Regions Together

EAPM believes that a framework is required for regular consultations with all stakeholders in the form of a Committee of Experts to be housed within the Commission. It is proposed that, in the interim, a taskforce be established to fulfil the same function.

This multi-stakeholder group would initially work for three years and have as one of its objectives the evaluation of the need for establishment of a formal committee by 2018.

The proposed group's scope will cover the use of data in healthcare which can include (but is not limited to) data from: clinical trials; biobanks; healthcare system transaction records; pharmacovigilance; medical records; prescriptions; consumers; patient-reporting; e-health; m-health; outcomes and; data from organisations.

In Vitro Diagnostics

On the morning of the same day, (14 September) EAPM will hold a meeting on IVDs at the Radisson Hotel, rue d'Idalie, in Brussels, to discuss issues including the definition of companion diagnostics; clinical evidence and a five-year transition period.

As the Luxembourg Presidency hopes to start negotiations with the European Parliament by October and reach agreement by early December, the timing of the workshop is important.

It will allow stakeholders to meet in order to understand the Council's and Parliament's perspective and for these institutions to understand that of the stakeholders.

Clinical Trials

EAPM held a Clinical Trials roundtable on 1 July, in Brussels, to expand upon the work begun at the ESMO conference in Madrid in 2014 and the intense efforts made over the last year, with more than 70 experts.

Under the heading 'Charting the course for a new cancer clinical research culture in Europe – the need for

transformative change', eight papers will be submitted for publication in a special issue of *Public Health Genomics*. These ask, in detail, whether the classic Randomised Clinical Trial approach is still the most optimal in the era of personalised medicine.

EAPM, its members and other key stakeholders believe that clinical trials must address, in a comprehensive and transparent fashion, the needs of all stakeholders and set the efficacy bars much higher than they are currently at the start of the process while introducing the concept of efficacy being linked to cost.

Harmonisation of efficacy and consideration of cost efficiencies at a European level has the potential to allow more equitable price negotiations to be conducted, which translates to more equitable access to innovative therapy for cancer patients.

In this era of stratified medicine, a well-defined biomarker strategy is crucial and must be embedded into the clinical trial process, with appropriate regulatory review and implementation based on best international practices.

On this topic, EAPM will host a roundtable during the ECCO Congress in Vienna (26 September) in order to create a hierarchy for solutions. This is primarily because the challenges need to be addressed in a sequential manner.

This forum will be followed by a meeting in early-to-mid November in order to present the group's proposals to MEPs and the European Commission.

The SMART Outreach programme

As mentioned in our last newsletter, the June EAPM conference introduced the Alliance's 'SMART' concept, which stands for Smaller Member States and Regions Together.

We intend to expand this by taking our message to other Member States over the coming months (and years) through our SMART Outreach programme.



Although Brussels-based – which helps to better engage with the European Commission, EU permanent representations and the European Parliament here 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.

The first event will take place on 9 September at The Economic Forum, in Krynica, Poland.

This will have a particular emphasis on Central and Eastern Europe, and examine the current state of play regarding personalised healthcare in the EU and the ways in which healthcare systems may need to adapt to accommodate it.

The first follow-up event is scheduled for 30 September, at the European Health Forum Gastein, in Austria, and two further Outreach events will take place later in 2015.

Luxembourg Presidency conference

This landmark conference, held on 8 July and supported by the Alliance, was a great success. The agenda featured many EAPM members as speakers or panelists, while the moderator was our co-chair Helmut Brand.

The Alliance was cited on many occasions and this certainly added to our profile in front of a packed audience of health ministers, a European Commissioner and even royalty.

Entitled ‘*Making Access to Personalised Medicine a Reality for Patients*’, the conference reflected what is one of the key elements of the current rotating presidency of the European Union and the results of this high-level meeting will eventually feed in to Luxembourg’s Council Conclusions in December this year.

The aim of the conference was to assess and address obstacles to the integration of personalised medicine into

Europe’s healthcare systems, identify best practices and the added value that such an approach can deliver, and outline the potential benefits that personalised medicine could have on public health and its impact on policymaking in the EU.

Luxembourg’s Health Minister, Lydia Mutsch (pictured above), said in her closing remarks: “If we want to address the integration of personalised medicine into daily care, in an efficient way, what we need is a patient-centred approach involving EU decision makers and regulators in the area of public health to enable the EU and Member States to contribute to the endeavour of making personalised medicine a reality.”

Summer School for HCPs

Also during the conference, plans for the Alliance’s 2016 Summer School aimed at training healthcare professionals were formally unveiled to attendees by Christine Chommiene (EHA), and the audience also heard about our calls for a European Translational Research Platform (ETRP).

Regarding the Summer School, the Alliance will hold a full-day meeting in Brussels on 8 September, with the objective of establishing an education curriculum for healthcare professionals (HCPs) dealing with necessary elements concerning personalised medicine.

The school will aim to attract many of Europe’s leading HCPs in order to develop, deliver and encourage uptake of personalised medicine, by building on practical approaches through an agreed curriculum.

The objective is for HCPs to learn, share and develop and the focus at this meeting will be on several areas such as diseases and genetic markers, ‘omics technologies and imaging markers, among others.

It is envisaged that the Summer School will take place either in June or July of next year.



4th annual Presidency conference

EAPM's fourth annual conference, in Spring 2016 will have 'Taking Stock' as its over-arching theme.

The two-day event, at the Solvay Library in Brussels (pictured above), will take as its format an opening plenary followed by five further sessions. These will feature high-level speakers and will be attended by some 180 experts. Further news on how to register will follow in due course.

e-learning

ecancer is tackling the emerging global challenge of personalised medicine head-on with the release of its new e-learning course.

Developed as part of the EU-funded 'P-Medicine' project, the modules cover a comprehensive range of topics, from molecular profiling to molecular imaging, choosing personalised treatments, and psychological support.

Each module is about 15 minutes long and freely available at ecancer.org

In the press

Recent EAPM-penned articles can be read by clicking on the links below.

[Changing times call for changing relationships](#)
[Over-screening for breast cancer brings little benefit](#)
[Data-sharing should include the patient too](#)
[Doctor-patient relationships must change](#)

About EAPM

The European Alliance for Personalised Medicine (EAPM) , launched in March 2012, brings together European health-care 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 European Medicines Agency. EAPM is funded by its members.

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