



European Alliance for Personalised Medicine

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EAPM steps up its SMART agenda

Welcome to our latest newsletter. During a highly successful third annual Presidency conference in early June (read the report by clicking [here](#)), EAPM announced its upcoming SMART Outreach programme, alongside plans for an Education Summer School in 2016.

On the same day, the Alliance – which is also heavily involved in the PerMed strategy – coordinated the launch of the Strategic Research and Innovation Agenda (SRIA) report with a meeting and press conference.

PerMed is a Commission-backed Coordination and Support Action (CSA) designed to bring together 27 national funders, as well as decision makers in research policy, health care and implementation. It is tasked with generating recommendations and research activities aimed at fostering the further implementation of personalised medicine.

EAPM believes that recognising the importance of translational research is crucial in terms of the integration of personalised medicine into European health systems, and has called for the development of a European Translational Research Platform (ETRP).

Meanwhile, as mentioned above, when it comes to the up-to-the-minute education of healthcare professionals, the Alliance's Education Working Group is striving to create an [Education Summer School](#) by the end of next June – an initiative supported by all the medical societies.

EAPM's main focus in this area will be on developing the plan, as well as a curriculum for future seasonal schools in Winter, Spring and Autumn.

The Alliance will be working to engage policymakers with a view to highlighting the need for more support for educational resources, a suitable framework, and recognition of professional qualifications at EU level.

The aim is to promote medical education, disseminate information, and exchange knowledge, technical and technological expertise between professionals working in

Coming up:

- 1 July: Clinical Trials round table to build on the work of our Working Group, Paris
- 8 July: Luxembourg Presidency conference on Personalised Medicine, Luxembourg
- 9 September: Launch of the SMART Outreach programme with a first event entitled 'Evolving Europe's healthcare systems'.

This will take place at The Economic Forum, Krynica, Poland

- 15 September: Meeting on In-Vitro Diagnostics - 'An overview of the state of play and consequences for stakeholders'

varied healthcare settings in resource-rich and resource-poor nations in the area of personalised medicine. Bridging the knowledge, technical and skills gap between professionals from diverse backgrounds will ultimately benefit patient in the era of personalised medicine.

Areas covered will be:

- Available diagnostic/prognostics/predictive tests and monitoring approaches; patient eligibility; data interpretation;
- Awareness of the latest relevant diagnostic prognostic, predictive and molecular tests, including monitoring possibilities garnered from the onset of Big Data;
- Monitoring developments in personalised medicine and on shifting competences from knowledge retention to information retrieval, and;
- Skills required to navigate the ethical, legal and social issues of diagnostics and monitoring in personalised medicine.

Christine Chomienne, of the European Hematology Association, has been appointed Chair of the Working Group and it was also decided that a patient representative will be her vice-chair.

To develop the curriculum with the group, a roundtable will be organised at the beginning of September, which will include medical societies and patients.



Clinical Trials

EAPM's Clinical Trials Working Group meets on 1 July and is seeking to respond to the challenges below, by creating a narrative of a policy and research agenda that could tackle them through multi-stakeholder collaboration.

The group is currently working on a series of nine articles that will be published in *Public Health Genomic*. These will seek to outline what solutions could be offered to:

- Optimise research to better address the objectives of different stakeholders with competing interests
- Optimise the finite opportunities to address important clinical questions in research
- Increase multi-stakeholder collaborations, especially cross border
- Better incentivise the successful development of biomarkers that can accelerate personalised medicine
- Optimise information sharing regarding existing research to avoid suboptimal clinical decision making that can delay the implementation of best practices in clinical research and practice

In addition to this, EAPM will organise a meeting in late October/early November to discuss to present the Special Issue of nine articles to the Parliament and European Commission.

Luxembourg to the fore

As mentioned earlier, on 1 July, Luxembourg will take over the EU's rotating presidency. The Duchy has already announced that personalised medicine will play a key role in its agenda and the first fruits of this will be seen at a **Presidency Conference** in Luxembourg City on 8 July.

The conference's main messages will form part of Council Conclusions to be adopted by the 28 health ministers during the December EPSCO Council.

The 'Outreach' programme

The recent EAPM conference introduced the Alliance's 'SMART' concept, which stands for Smaller Member States and Regions Together. This forum was held under the auspices of the Latvian Presidency and also gave a platform for the upcoming Luxembourg term, and a major conference in which EAPM is very much involved on 8 July.

It is time to take the messages delivered at successive EAPM Presidency conferences, European Parliament roundtables, and stakeholder congresses directly to national level. With this in mind, the Alliance will set up a formal steering group of members that can reiterate those messages on home soil. This steering group will be made up of stakeholders representing patients, medical professionals, healthcare planners and industry representatives, as well as scientists and researchers.

The steering group will meet regularly and act as a point of contact for EAPM's work in the wider Europe to ensure that there is effectiveness and coordination in the regulatory, policy, education, and engagement arenas. It will also serve as a link to the STEPs interest group of MEPs, the European Commission and national Members of Parliament.

The Alliance believes that, among other things, SMART will allow it to follow, in a practical way, the key implementation of legislative dossiers in individual countries, while offering an opportunity to develop a core group of stakeholders to facilitate activity on the ground in Member States and support the Alliance at EU level.

As part of its work with smaller Member States, EAPM will begin its 'Outreach' programme during 2015, and continue it into the future. This will be called 'SMART Outreach - Pathways to Personalised Medicine' and this year will see several events.

Moreover, in 2016, up to five further events will take place (subject to the necessary funding) and, where relevant, will tie into the Conclusions of upcoming EU Presidencies.

Event I:

Evolving Europe's healthcare systems
9 September 2015, The Economic Forum, Krynica, Poland

With a particular emphasis on Central and Eastern Europe,



SMART

Smaller Member States And Regions Together

this event will 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.

A discussion panel will be organised in cooperation with the Polish Ministry of Health and EAPM, building upon the SMART initiative focused on developing personalised healthcare policies in smaller Member States and regions.

Experts and policymakers from Central and Eastern Europe will share their views on the future shape of healthcare systems, focusing on improving access to early diagnosis to facilitate getting the right treatment to the right patient, as well as the financial schemes for modern therapies.

Event 2:

An inter-institutional discussion: 'Personalised Medicine – the right treatment for the right patient at the right time'
17 September 2015, Sofia, Bulgaria

The meeting will attempt to address the broad issues below with a view to aligning EAPM's personalised medicine STEPs agenda with those at the national level.

Sessions will address:

- Personalised medicine – the concept, principles and methods, plus the advantages for patients and healthcare systems
- Access to methods and products of Personalised medicine

High level speakers will include:

- Dr Peter Moskov, Minister of Health of the Republic of Bulgaria
- Dr Daniela Daritkova-Prodanova, Chairperson of the Health Commission of the Bulgarian Parliament

- Dr Andrey Kovatchev, Member of the European Parliament
- Dr. Stanimir Hasyrdjiev, Member of the Board of the EPF, Chairman of NPO, and Secretary General of the EU Partnership for Improvement of Patients' Access to Healthcare

Event 3:

New regulatory pathways for personalised medicines
30 September 2015, European Health Forum Gastein, Austria

This event will examine the progress in developing Medicine's Adaptive Pathways to Patients (MAPPS) to help bring new specialised medicines through clinical trials and safety and approval processes faster and in manner that takes into account reduced target patient populations.

It will also look at the choices that developers of new medicines will need to make in progressing potential new medicines through the regulatory process. The session will also consider the US's development of Breakthrough Designation-status medicines.

Contributions will also come from senior EU regulators, policymakers, EAPM members including clinicians, patients, industry represented by AstraZeneca and regulatory affairs leaders.

Event 4:

Rewarding innovation, optimising resources
Late autumn 2015, Brussels, Belgium (date TBD)

This event will bring together officials from the European Parliament, the Commission, the European Council and industry, as well as patient groups and academic researchers. The event will look at how the new era of personalised healthcare and medicines might be paid for.



For example, is personalised medicine unaffordable or can new mechanisms be developed and introduced that will reward innovation and allow access to new medicines for patients within the confines of Europe's healthcare budgets?

The event is intended to provide a bridge between Luxembourg's and The Netherlands' EU presidencies.

EAPM 4th Presidency conference

EAPM's fourth annual Presidency conference, in Spring 2016 under the EU Presidency of The Netherlands, will have 'Taking Stock' as its over-arching theme.

The two-day event, to be held at the Solvay Library in Brussels, will take as its format an opening plenary followed by five further sessions.

As for the past three conferences, these sessions will include a powerful array of high-level speakers and will be attended by some 180 experts. As always, these will include MEPs, government ministers, Commission officials, EMA representatives and EAPM members drawn from patient groups, healthcare professionals, industry, academia, research and the media.

There is a clear value to stakeholders in attending this conference and dates and a registration link will be provided in due course.

Meanwhile, EAPM's next newsletter will be distributed in early September.

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 European Medicines Agency. EAPM is funded by its members.

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