



# European Alliance for Personalised Medicine

**EAPM Bulletin: Issue 3, April 2015**

## EAPM conference coming soon

Welcome to EAPM's third newsletter of 2015 and, if readers were not already aware, the Alliance's third annual conference, to be held in Brussels under the auspices of the Latvian Presidency, is only seven weeks away.

There is only limited time and space so we invite you to register as soon as possible by clicking [here](#).

This year sees two smaller nations at the helm of the European Union. Current president Latvia will be followed by Luxembourg on 1 July and EAPM is working with both to help further the cause of personalised medicine.

The Alliance believes that health policies need to recognise and tackle the inherent health system vulnerabilities faced, specifically, by smaller countries and in the regions of the larger ones. We call this a **SMART** approach – Smaller Member states And Regions Together; and this will be further developed at the conference on 2-3 June.

With this in mind, this year's conference is entitled 'Smaller Member States And Regions Together (SMART): STEPs in the Right Direction to a Brave New Healthier Europe'. Among the high-level speakers will be the Health Commissioner, the health ministers from Latvia, Luxembourg and Malta, and several, cross-party Members of the European Parliament.

These will be joined by the most influential stakeholder representatives driving personalised medicine during six plenary sessions on the following topics:

- *'State of Play' of ensuring better treatments for patients*
- *Learning from Smaller Member States and Regions*
- *Medical Adaptive Pathways – Taking Steps Forward*
- *Strengthening Patient-orientation and Personalisation: Overcoming Barriers to Equality and Solidarity: Patient Access*
- *Personalised medicine and a European Big Data-driven economy – The Lighthouse Effect*
- *Unlocking the value of research to provide evidence, and education of healthcare professions*

### April and May at a glance:

- 16 March -

The sessions, representative of EAPM's membership (patients, medical professionals, healthcare planners, industry, scientists and researchers), reflect the solid work programmes developed since the Alliance's formation and, from these discussions, a set of recommendations will emerge which EAPM hopes will support and strengthen Luxembourg's Council Conclusions on Personalised Medicine due later in the year.

It promises to be a lively and productive two days and we hope to see you all there.

### Read all about it...

The Alliance is always working to spread the word and explain the benefits of personalised medicine to the wider world.

With this in mind, EAPM is continuously writing and placing articles in various media. A recent one was entitled ***Together, we can realise the dream of personalised medicine*** and it can be found [here](#).

Also worth checking out on a regular basis is our ever-developing conference website, which you can visit [here](#), while the latest conference booklet can be viewed [here](#).



EU2015.LV

## Latvian Presidency of the Council of the European Union

### In the PM pipeline

Also upcoming will be a series of workshops and roundtable meetings in order to further develop the **SMART** themes that include value, access, patient-centric approaches, empowerment and a focus on translational research.

As well as the topics to be covered in the flagship conference, part of EAPM's focus will be on pushing for a Lighthouse Initiative for Personalised Medicine to be included in the Big Data Value Partnership.

Meanwhile, the Alliance is maintaining its work in the area of clinical trials and a Consensus Document, formulated after upcoming consultation with EAPM members, will be available in due course. Find out more about these in this newsletter.

At the same time, EAPM is working alongside the PerMed consortium, a Coordination and Support Action (CSA) financed by the European Commission in order to deliver a Strategic Research and Innovation Agenda (SRIA).

The aim is to develop recommendations to foster the implementation of personalised medicine in relation to research funding, as well as the present and future potential of health systems.

### Surveying the landscape

Also ongoing is our recently launched Personalised Medicine Survey - Literacy among Healthcare Professionals

The issue of education of healthcare professionals is a major one. It is clear that a great degree of up-skilling is already required and, to keep pace with the science, this must be ongoing.

The Alliance has called for action at EU level, saying: "By 2020, the EU should support the development of a Europe-wide education and training of health care professionals' curriculum for the personalised medicine era, by committing to this in 2015. The EU should subsequently facilitate the development of an "Education and Training

Strategy for Healthcare Professionals in Personalised Medicine."

But in order to increase personalised medicine literacy, it is necessary first to determine the current state of understanding and knowledge gaps amongst European healthcare professionals.

Along with its stakeholders, EAPM has developed a two-step strategy to measure the current level of literacy. This process was begun under the Italian Presidency of the EU last year and will underpin a collaborative approach to increase the knowledge base and appreciation of the key benefits and challenges of personalised medicine.

The first step in this process is the evaluation of current levels of PM literacy with a focus group of stakeholders.

The questionnaire is divided into 36 questions and will take around 20-25 minutes to complete. It will remain completely anonymous.

The second step will be the evaluation of current levels of literacy through a quantitative structured series of questions which would be the subject of a voting poll.

The results garnered from this poll will be analysed and prepared for scientific publication and will inform the development of a PM education strategy going forward, leading to the production of an educational toolkit that enhances PM knowledge and contributes to the embedding of personalised medicine into European health systems.

### Clinical trials

***Unlocking the value of clinical research to provide evidence for today and tomorrow's discoveries***

This committee is co-chaired by Gabriella Pravettoni, Paolo Casali (Methodology/Patient Empowerment), Sabine Tejpar (Biomarkers) and Roberto Salgado (Clinical Trials frameworks).

The convergence of new biological insights from sequencing technologies and advanced bioinformatics tools is creating

new opportunities to advance cancer care for individual patients. Fully realising this potential will require the integration and alignment of multiple stakeholders across the healthcare arena.

EAPM has organised a multi-stakeholder personalised medicine-focused panel to address how oncology clinical research can better support delivering the right treatment or prevention to the right patient at the right time.

Increasing the speed at which personalised medicine discoveries are translated into clinical practice requires appropriately conducted clinical research with input from patients, healthcare providers, regulatory authorities and policy makers. These stakeholders need to align in establishing the right evidence to facilitate access to personalised treatments addressing the needs of targeted populations.

There is a need for tools to individualise clinical decisions at the patient's bedside.

Readers will understand that personalised medicine is all about tailoring treatment to the characteristics of the single patient. Of course this first requires us to take into account available evidence, since personalised medicine needs to stand firmly within the domain of evidence-based medicine. At the same time, however, every piece of evidence needs to be exploited to fit the needs of the patient, since all characteristics pertaining to the individual patient should be valued in principle, and all the evidence may be crucial for this.

### ***Two processes are involved***

The first process lies in selecting all pieces of evidence which may be relevant and combining them with each other. In the end, this should give rise to a personalised probability distribution for any given outcome.

For example, a patient may have a disease which was demonstrated to be sensitive to a specific treatment through a randomised clinical trial. However, the magnitude of benefit shown by the trial refers to an ideal "average" patient. How much do the characteristics of all patients involved in the trial overlap with those of the single patient? This will help the clinician to adjust probabilities to the single patient.

For example, a patient's age, and thus his/her life expectancy, may substantially change the benefit in duration of survival one may expect, which may differ from the median survival shown in the trial.

This will be discussed in the final document, as will the second process. This involves factoring the values of the single patient. For example, a patient may value the toxicity involved in a treatment in a highly individualised way.

Thus, the resulting quality of life might be perceived in a completely different way from the median impact demonstrated in the "average" patient of a clinical trial. The patient and the doctor should come to a shared clinical decision modelled on the patient's own individual values.

### ***Current challenges include:***

- *Multiple research questions need to be addressed to support decision making by a wide-range of stakeholders, often with competing interests and objectives*
- *There are finite opportunities to address research questions*
- *There is a lack of collaboration and integration on research projects among different stakeholders*
- *There is inefficiency in how information is disseminated and shared regarding research*

## **A Lighthouse Initiative for Personalised Medicine**

The European Commission, in its Communication '*Towards a thriving data-driven economy*', calls for the EU to support 'lighthouse' data initiatives capable of improving competitiveness, quality of public services and citizens' lives. These initiatives maximise the impact of EU-funding within strategically important economic sectors.

The Communication presented personalised medicine as one of the possible target areas.

The creation of the Big Data Value Association (BDVA) and the European contractual Public Private Partnership (cPPP) on Big Data Value brought forward two powerful vehicles to

support the development and adoption of data centric initiatives that can contribute positively to the socio-economic and technological progress of Europe.

A focus on personalised medicine would be very beneficial to Europe as it has massive potential to make treatments more effective (with fewer side effects) and more cost effective.

Creating a Data Ecosystem for Personalised Medicine in Europe would yield multiple benefits. Not only would it accelerate the development of more effective treatments and potentially help with the management of healthcare resources as described above, it would also act as a foundation for private sector investment and jobs in R&D in Europe.

EAPM is working hard to make a Lighthouse Initiative for Personalised Medicine a reality through the BDVA.

As ever, all of EAPM's work has the goal of stimulating informed debate, interaction and collaboration over the vital health issues that face us all, now and into the future.

## STEPs group MEPs awarded

Three MEPs involved with the Alliance and who have spoken at the STEPs campaign meetings recently won MEP awards for their work.

**Alojz Peterle** won the health award for the third time; and told the audience of his "surprise", adding: "Our motto should be health first and until this is true, we cannot say we have been truly successful."

The Regional policy award went to **Lambert van Nistelrooij** who thanked his fellow MEPs for this "wonderful award",

while **Sirpa Pietikäinen** received the animal welfare award. Sirpa told the audience that "the way we treat animals tells us what kind of people we are and how we treat other people".

EAPM is delighted to have these high-achieving MEPs among its supporters and offers its congratulations on their awards.

### 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.

Contact: Denis Horgan  
EAPM Executive Director  
Avenue de l'Armee/Legerlaan 10  
1040 Brussels, Belgium  
Ph: + 32 4725 35 104  
Website: [www.euapm.eu](http://www.euapm.eu)

