



European Alliance for Personalised Medicine

EAPM Bulletin: Issue 13, April 2016

www.euapm.eu

Alliance 4th conference just days away

Welcome to EAPM's April newsletter, and we have plenty coming up during Spring and Summer 2016.

Despite the tragedy of the Brussels bombings recently, such acts are, as we all know, extremely rare in the Capital of Europe, regardless of the occasionally alarmist stance of the national and international media. All our events in the city will go ahead as planned.

Although a young alliance, as readers will know EAPM's achievements in the field of personalised medicine have already been notable.

A highly successful debut conference, held under the auspices of the Irish Presidency of the EU in Dublin, 2013, and two follow-up events in Brussels in 2014 and 2015 (under the Italian and Luxembourg presidencies respectively), have been augmented by numerous position papers, high-level workshops, a swathe of press coverage and cross-party backing from influential MEPs.

The Alliance's fourth annual conference, to be held once again in Brussels at the historic Bibliothèque Solvay on 5-6 April, will build on these solid foundations and aims to raise awareness among policymakers about the needs of modern-day patients and how personalised medicine has the potential to change healthcare for the better.

Taking Stock: Where we are now and the necessary next steps

The Alliance played a major part in the Luxembourg Presidency's summer conference, and reacting to the Grand Duchy's [Council Conclusions](#). (which featured much EAPM input) will play a significant role in the April conference.

Plenary sessions at the EAPM event will cover the topic of 'Taking Stock' as seen from several perspectives: The Member States, the European Commission's, and the Stakeholders'.

Also being discussed in plenary will be: 'HTA – Payer - Integration'; 'Value of Innovation, Access and Incentives'; and 'Genetic Mapping & Ethics'.

The conference will also feature roundtables on 'New models for clinical trials'; 'The Data Protection Regulation and Big Data generally'; 'The promotion of cross-disciplinary interaction'; as well as a 'Diseases Focus' session.

At Bibliothèque Solvay, high-level speakers and attendees

In the pipeline

- **5-6 April: 4th Annual Conference, Bibliothèque Solvay, Brussels**
- **11-12 April: Research Working Group roundtables, University Foundation, Brussels**
- **1-2 June: PerMed conference on personalised medicine, Brussels**
- **4-8 July: Summer school for HCPs, Cascais, Portugal**

will come from a wide range of stakeholder groups including patients, healthcare professionals, academics, industry representatives, politicians and legislators, the media and more.

The event will be held across one-and-a-half days, and the aim is to see real and concrete recommendations emerge.

Click [here](#) to register and [here](#) for the conference agenda.

TEACH Summer School

EAPM will run its first Summer School for young healthcare professionals (HCPs) in mid-2016.

Entitled 'TEACH' (Training and Education for Advanced Clinicians and HCPs), the school will be held at various cultural venues in Cascais, near Lisbon, Portugal, and will run from 3-7 July.

Four museums have been chosen as the venues for the summer school sessions.

Personalised medicine is now at the centre of most, if not all, aspects of patient care. It is not limited to rare diseases or cancer, but spans all medical specialties. This exciting new way of treating patients is, however, based on specific concepts or biological pathways in a field which is continuously moving.



This means that all healthcare professionals in close contact with patients or their families need to possess a solid knowledge of the current aspects of personalised medicine and its latest breakthroughs, in order to better understand patients' concerns.

The Alliance is firmly of the belief that health-care professionals cannot be expected to adapt to new ways of approaching patients and coping with new technology unless they are suitably trained.

These HCPs are being asked to move beyond traditional reactive medicine towards proactive healthcare management, employing screening, early treatment, and prevention, and to classify and treat diseases in a new way, interpreting information from across sources that blur the traditional boundaries of individual specialties.

Professionals will need to be confident of the science behind targeted therapies, including greater understanding of the immune system and molecular medicine, and knowledge of the mechanisms of action and interaction of targeted therapies, as well as common adverse events.

To this end, the Alliance will run its summer school aimed at bringing 80 young professionals and patients (aged 28-40) up to speed with doctor-patient communication skills. The summer school also aims to support the endeavours of EAPM to set up a Continuous Educational Programme on personalised medicine.

The training will consist of plenary sessions followed by time spent in small groups focussing on how to communicate in respect of several defined topics over the course of four days.

Tutors will be chosen from medical academic, clinical and research specialties, patient organisations and communication specialists.

The school has its own dedicated section on the EAPM website, so see more and register, [click here](#)

Genomics for Health

'Genomics for Health' is a campaign initiative driven by EAPM in conjunction with its multi-stakeholders partners which includes the patients, medical professionals, healthcare planners, industry, scientists, researchers and STEPs MEPs Interest Group in the European Parliament

The 'Genetics and Mapping' section of the Alliance conference will bring policy makers together with those leading the implementation of the young and exciting science of genomics into healthcare.

Utilising EAPM's Working Group on Big Data, the initiative's aim is to engage and inform European Union and Member State policy makers in order to shape the landscape for the successful implementation of genomics and related technologies in the healthcare arena.

The goal is to achieve a stakeholder-driven consensus on six key pillars

- Agree standards for data generation and analysis, plus genomic sequencing and analysis

(Define standards that will ensure consistency of clinical testing and greatly further research)

- Data privacy and sharing - Agree guidelines around the sharing of genomic and associated clinical data

(The sharing of data greatly increases the utility of genome sequencing in, for example, confirming pathogenicity of an identified genetic change and identifying other patients with the same rare disease.)

- Clinical informatics - Promote the uptake and alignment of existing agreed standards and define principles for interoperability of health informatics systems

(The linking of clinical to genomic data is essential to derive the benefit from genomic data, for both health and research purposes.)



- Clinical application - Coordinate national activity to ensure shared best practice, clinical implementation and application

(A coordinating body is necessary to ensure that models of best practice for clinical implementation and application are shared.)

- Clinical education - Structure a training programme in genomics, informatics and personalised medicine for clinical staff

(For patients to be correctly identified for the most relevant test, and the appropriate information from results to be conveyed back to them, this educational deficit must be addressed among health care professionals.)

- Framework - Promote broad discussion with European regulators on the appropriate mechanisms for clinical genomic testing

(Current regulatory mechanisms can make the rapid implementation of effective innovative diagnostics to patients challenging, particularly as genomic tests.)

Where genomics in health stands today - and its incredible potential through Next Generation Sequencing and more - will be presented, backed up by discussions on key challenges to progression, differing perspectives and the development of a high-level plan for advancement in this crucial area.

Topics to be covered during the event will include improving treatment selection in cancer, maximising success of diagnosis in rare diseases, and what (regulatory) framework is best to support innovation in genomics.

Genomics is the foundation that enables the vast potential of personalised medicine to be realised, much of it preventative.

With rising healthcare costs and individual health systems being increasingly challenged, 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.

This will ease the burden on healthcare systems and lead to a healthier and, thus, wealthier, Europe. The potential for bettering the health of the EU's 500 million citizens across 28 Member States is huge.

High-level conference, Milan

On 7 March, high-level stakeholders in personalised medicine from across Italy and the rest of the EU met in Milan to move forward with this innovative form of medical intervention tailored to the specific needs of individual patients.

The conference, part of EAPM's SMART Outreach programme, saw the launch of the Italian Alliance for Personalised Medicine and, like other Outreach events in Poland, Austria and Bulgaria, worked towards formulating a patient-centred strategy involving national decision makers and regulators in the arena of public health, to enable the EU and Member States (such as Italy) 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 concentrated on



how Italy can contribute to this at EU level and how it can be enhanced at the national level.

The conference was deemed a great success by all who attended and planning is now underway for similar events in Ireland (May) Spain and Germany (both in June).

Watch the video, [here](#)

Roundtables

EAPM is co-ordinating a two-day series of roundtables, with key Member State, Commission and wide stakeholder input, on five key challenges associated with research and personalised medicine.

The event will occur over Monday and Tuesday, April 11-12 and is heard towards feeding into a Commission/ICPerMed conference on personalised medicine to be held on 1-2 June, in Brussels.

EAPM will organise a follow-up meeting, possibly in September, to further these important topics.

The workshops follow on from the PerMed 'Strategic Research and Innovation Agenda' (SRIA) on Personalised Medicine, launched at a press conference last June in Brussels.

The Commission, Member States and EAPM, alongside other stakeholders, are striving to develop a roadmap for research that aims to embed personalised medicine approaches into European health systems and acknowledges the need to identify "exemplars" which can be tested as models for effective translation of research into clinical benefit, as well as showing "added value".

Europe not only needs world-class research, it requires a regulatory framework, and an economic model, that will allow

new drugs not only to be developed but also to be made available to patients who need them, wherever they need them, across Europe.

Citizens need to benefit from better co-ordination of research with all stakeholders involved, including a cross-section of legislators in the European Union.

Europe is still at the very early stages of translating research results into actual products. Research is key, as is a focus on innovation in health care.

Attendees at the workshops will be made up of researchers, academics and high-level experts on many aspects of personalised medicine.

The five crucial areas are:

Developing Awareness and Empowerment

Through personalised medicine, the role of HCPs and patients will evolve. Patients and healthcare professionals need to develop the required awareness and a first step is to deliver best available evidence supporting the clinical and personal utility as well as the economic value of new approaches to health systems.

Translating basic to clinical research and beyond

In order to achieve its anticipated impact on the health and well-being of citizens, translation of discoveries and communication across the continuum of research are required. This starts with the integration of all the 'omics' data to generate and implement meaningful interventions and diagnosis.

Shaping Sustainable Healthcare

Personalised medicine will rely on healthcare systems that are able to adapt to these approaches in a timely and socially acceptable manner, while enabling the participation of all stakeholders to increase effectiveness. Training for health



professionals is required as is the promotion of engagement and close collaboration between all stakeholders, including patients.

Integrating Big Data and ICT Solutions

The development of personalised medicine will rely heavily on integrated Big Data analytics and ICT solutions to generate and integrate the required knowledge and infrastructure for new approaches. Technologies for data capture as well as the management and development of high-quality databases will be as instrumental as strategies to make sense of data for known and future purposes.

Bringing Innovation to the market

Innovative solutions represent a higher uncertainty regarding going to market. There is a need to develop new risk-based approaches for their evaluation in a context that encourages systematic early dialogue with all stakeholders providing guidance for companies.

In the news

As ever, EAPM has had several articles published in the media recently, the first one of which celebrates the achievements of several MEPs who have consistently supported the Alliance and its goals. Simply click on the titles below.

[Personalised medicine-backers honoured in MEP awards](#)

['PRIME' scheme should bring access to new drugs close](#)

[Speedy introduction of new, efficacious drugs saves lives](#)

[High-level Warsaw meeting embraces personalised medicine](#)

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**