



# European Alliance for Personalised Medicine

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## Alliance members working in HARMONY

Welcome to EAPM's September newsletter. The Alliance hopes you all had an enjoyable summer break and is looking forward to continuing the work and clear progress that has characterised EAPM from its foundation.

### HARMONY project

EAPM has become involved with an IMI-funded project called HARMONY. This stands for Healthcare Alliance for Resourceful Medicines Offensive against Neoplasms in HematologY.

HARMONY will be a European Network of Excellence that captures, integrates, analyses and harmonises Big Data from high-quality multidisciplinary sources for the purpose of acquiring valuable knowledge across the spectrum of hematologic malignancies (HMs).

The project, which has 51 partners across ten different countries, will focus on HM disease areas with a high unmet need, namely multiple myeloma, acute myeloid leukemia, acute lymphoblastic leukemia, chronic lymphocytic leukemia, non-Hodgkin Lymphomas, myelodysplastic syndromes, and pediatric HMs.

The HM-specific Big Data platform developed by HARMONY will enable the rapid definition of promising treatment strategies, and prediction of adverse events likely to be associated with such strategies.

Organisers says that the HARMONY platform "represents a tool to determine treatment options for the individual patient, and to make its application easier the platform will take into account demographic differences, as well as the needs of the individual patient".

It aims to improve reliability, and therefore the value of the data, and will specifically address the need to define standard sets of outcome measures that are relevant to all stakeholders, and that will help monitor treatment.

The Alliance is taking the lead for one of the work packages, which is entitled: Payer/provider, HTA, EMA alignment and optimisation (WP6).

The main objectives of WP6 are:

- To develop an 'evidence framework' for centralised regulatory approval and national/regional HTA across EU Member States to support the decision-making processes for market access of innovative medicines for HMs

### In the pipeline

- **7 September: EORTC session with EAPM - "Are we locking the gate to personalised medicine in cancer?"**
  - **12 -13 September: PACT event in Sofia, Bulgaria**
  - **15 September: SMART Outreach event in Madrid, Spain**
  - **22 September: SMART Outreach event in Berlin, Germany**
  - **26 September: Outreach in Bologna, Italy**
  - **3 October: SMART Outreach event in Warsaw, Poland**
  - **6 October: Outreach in Belfast, N. Ireland**
  - **8 October: EAPM oncology roundtable at ESMO Congress, Copenhagen, Denmark**
  - **11 October: EAPM Access/Diagnostics roundtable during MedTech Week.**
  - **November: IVD regulatory workshop**
- To develop a 'clinical value framework' to assess the magnitude of clinical benefit /added therapeutic value offered by a new medicine in relation to available therapies for a given HM, integrating feedback from relevant partners in the scope of their respective responsibilities

- To ensure dissemination of main findings to stakeholders, increasing their health literacy regarding HMs and their active engagement with the project, aiming at sustainable long-term implementation of the project outcomes



# SMART

Smaller Member States And Regions Together

## EAPM and EORTC

On 7 September, EAPM's executive director Denis Horgan will chair a session entitled "Are we locking the gate to personalised medicine in cancer?" at a key EORTC event.

The event itself is called: "Navigating Safely Through the Regulatory Triangle" and will be held in Brussels.

## SMART Outreach

The Alliance's June 2015 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 SMART Outreach events have already been held in Poland, Austria, Bulgaria, Romania, Germany and Italy and more are planned this year at venues in Spain and Portugal.

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.

Several SMART outreach events are coming up soon and will take place in September and October in Sofia, Madrid, Berlin, Bologna, Krakow, Warsaw, and Belfast (for dates, see the 'In the pipeline' box on Page One).

EAPM is moving forward with the national Outreach programmes and the Alliance sees such a strategy as the natural next steps for the organisation.

The events aim to establish a network at the national level to support the Alliance, while assessing and addressing obstacles to the integration of personalised medicine into national and EU healthcare systems.

Other goals include identifying best practices and their added value which can be replicated across the EU, and outlining the potential benefits of personalised medicine on public health and its impact on policymaking at the national level.

EAPM is also helping to set up national alliances. In Spain, for example, the meeting at Centro Nacional de Investigaciones Oncológicas (CNIO), Madrid, on 15 September will see the formation of a network for the Spanish Alliance for Personalised Medicine (SAPM).

The event will formally launch SAPM under the EAPM umbrella and banner. The SMART Outreach programme is ideal in a nation that has many distinct regions (SMART stands for Small Member states And Regions Together).

The same will happen in Berlin, Germany on 22 September to launch the German Alliance for Personalised Medicine (GAPM).

A few days later, in Italy, EAPM will host a meeting in the historical capital of the Emilia-Romagna region, Bologna, and the full-day event will see a meeting of the Italian Alliance for Personalised Medicine (IAPM), which was launched in Milan earlier this year, followed by an EAPM annual general meeting to present an overview of activities and goals, as well as to appoint new members to the board.

In consort with EAPM's 'Taking Stock' theme at the 2016 annual conference held in April, the new national Alliances will be analysing where stakeholders should go next relating to the implementation of the Council Conclusions on personalised medicine drawn up during the Luxembourg EU Presidency.

Meanwhile, EAPM's Executive Director Denis Horgan will present the Alliance's work at the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations and Healthcare Professionals' Organisations joint meeting (20 September).

Much of this will relate to matters identified by the members in the Special Issue on [Clinical Trials](#) and the Special Issue on [Access and Value](#). Click the titles for links.

Aside from this, EAPM will once again be highlighting the key issues relating to recent regulations that have passed through the European Parliament (rulings on data protection, clinical trials and in-vitro diagnostics). And, of course, we will continued to engage with MEPs and the Commission in respect of the implementation of Luxembourg's Council Conclusions.



## Looking ahead to 2017

EAPM also already has much planned for 2017, including its annual conference (in association with the Maltese Presidency of the EU) and continued work in the regulatory area.

Also, from January-May 2017 there will be further Outreach meetings in Spain, Romania, Germany and Italy, plus further work on Translational Research.

Read more in our 'Forward Together' document, available [here](#).

## TEACH Summer School

TEACH stands for Training and Education for Advanced Clinicians and Healthcare professionals (HCPs), and the inaugural event held in Cascais, Portugal, in July was deemed a great success, both by organisers and attendees.

Christine Chomienne, a key player in the event and a past-president of the European Hematology Association, said on the last day of the event: "It was wonderful and exciting to see that so many young professionals enrolled."

She added: "All HCPs in close contact with patients or their patients' families need to be up-to-date with the current aspects of personalised medicine and its latest breakthroughs in order to better understand their patients' concerns.

Attendees from more than 20 countries gathered in Cascais and the faculty put in place by EAPM and its stakeholders and partners had a similar EU-wide spread.

Topics and specialised areas covered across the week included respiratory diseases, oncology, pathology, imaging, cardiology, genomics, pharmacogenomics and hematology.

Coming up in the next few months will be follow-up webcasts aimed at the healthcare community.

You can read the post-event report, [here](#).

## Regulatory workshop

The Alliance will hold an IVD Regulatory Workshop later this year (November).

The title of the workshop is: ***Shifting Sands: Finding our way in the new regulatory terrain of In Vitro Diagnostics medical devices in Europe.***

Also planned (this time for 2017) is a high-level congress (venue to be decided), running over three days.

While much has been achieved through stakeholder interaction at the four EAPM conferences, with involvement from policymakers/regulators, MEPs, national healthcare officials, patient groups, HTA bodies, academics, researchers, healthcare professionals, industry representatives and more, the Alliance believes that the time has come to find practical on-the-ground ways to turn the dream of personalised medicine into reality.

This essentially means the practical integration of personalised medicine into Member State health care systems as swiftly and efficiently as possible. Clearly, at Member State level there are substantial differences and among those needing to be addressed are:

- Cross-border healthcare availability, especially in the smaller, often less-rich countries
- Wildly fluctuating costs of the same treatments and medicines
- Huge variations in reimbursement procedures
- A lack of agreement/consistency across Member State HTA bodies
- Cross-border collaboration in, for example, research (sharing knowledge and avoiding repetition)
- Interoperability issues
- Effective ways of gathering, storing and sharing Big Data
- Agreeing pan-EU best-practice guidelines



- Education for HCPs across all Member States
- Awareness raising of personalised medicine among the media and general public

All of the above are problems that require solving, quickly, if we are to see the right treatment for the right patient at the right time for every one of the EU's 500 million citizens regardless of where they live and their financial status. The Congress will aim to address these issues.

### In the news

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

[Politics won't stop the march of genetic innovation in medicine](#)

[Health decisions remain on political playing field in US and Europe](#)

[Going for gold – but refugees are not just at the Olympics](#)

[The challenge of dovetailing improved trade with improved EU health](#)

[Access for patients to best treatments is an issue both sides of the Atlantic](#)

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### 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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