



European Alliance for Personalised Medicine

EAPM Bulletin: Issue 10, December 2015

www.euapm.eu

Alliance working groups await Luxembourg Council Conclusions, due this month

Welcome, all, to our latest newsletter.

November has seen an especially busy month for the Alliance's Working Groups, which have identified their priorities for 2016. These are primarily to analyse the Luxembourg Council Conclusions on personalised medicine, due in early December, and help to realise the proposals within them.

This will involve developing position statements on key issues via roundtable discussions in January and following these up with Member States and the European Commission, among others.

The working groups on Translational Research, Big Data, Value/Innovation, Education and Training of Healthcare Professionals and the task force on Regulatory Affairs will all have plenty to do.

Meanwhile, EAPM has published a series of articles in an international online health magazine as part of the work of its EU Consensus Group on Clinical Trials.

The articles have appeared in a special edition of *Public Health Genomics* under the title 'Getting Personal: The Future of Medicine and Clinical Trials'.

The articles attempt to address whether a personalised medicine enabled clinical research and trial strategy can produce better outcomes for cancer patients across Europe's 28 member states.

More than 1.75 million citizens die from cancer every year in the EU, and Europe's ageing population will significantly increase the incidence of cancer over the next two decades.

The authors have stated that: "Now is the time to deliver focused solutions that will improve outcomes for cancer patients in Europe."

An important part of the work undertaken by EAPM concerns clinical trials and patient access to them. Indeed,

Coming up in December:

- 14 December, 10-12.00: EAPM stakeholders will discuss 'Disruptive Innovation: Launch of public consultation on preliminary opinion'

The intention is to draft a reply to this document from the European Commission's Expert Panel

- 14 December, 13-16.00: Internal meeting to present an overview of activities to members, as well as outlining EAPM's plans for next year

one of the four-year-old Alliance's main aims is tackling the broader issues of personalised medicine in terms of clinical trials, as well as biobanks, data sharing, EU regulations and more, while looking towards the EU's Horizon 2020 initiative.

You can read more, [here](#).

2016 EAPM Conference

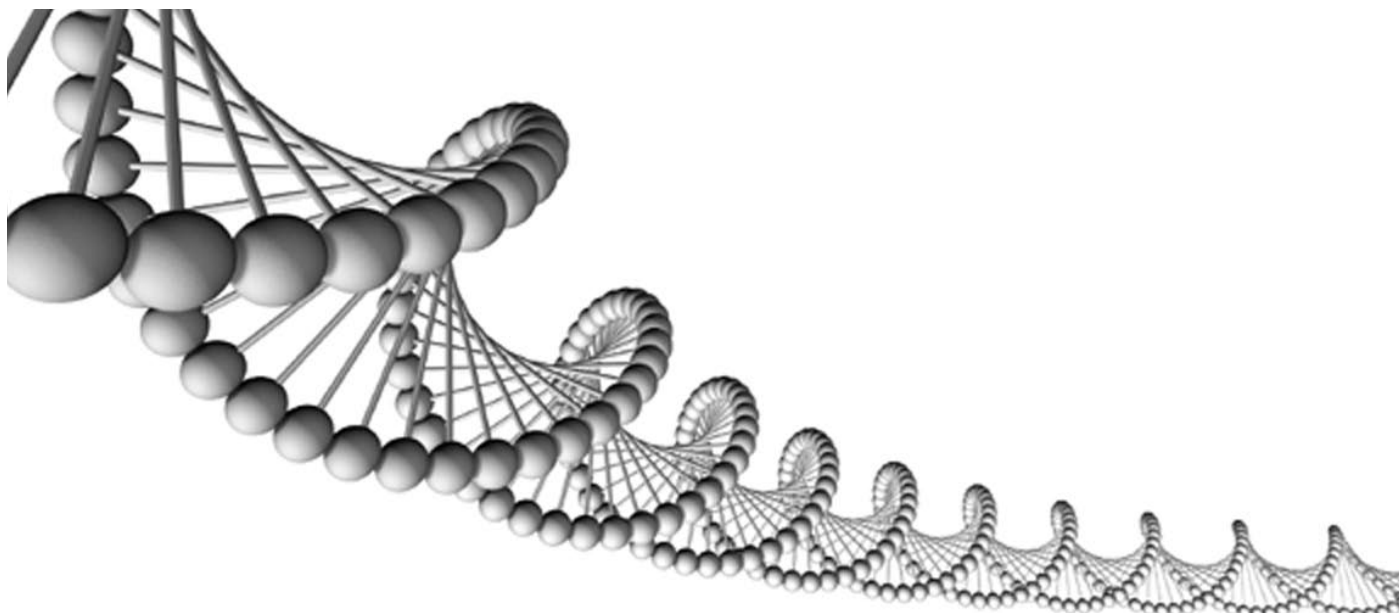
The draft agenda for our next conference will be circulated in the next few days.

Working on the theme of 'Taking Stock - Where we are now, and where we need to go', this 4th annual event will take place in early April at the prestigious Bibliotheque Solvay, close to the European Parliament in Brussels. The conference will, this year, fall under the Dutch Presidency of the EU.

Alliance responds to Expert Panel

The Alliance responded to a potentially highly influential Opinion on health services from a European Commission Expert Panel.

The public consultation on the preliminary opinion on



'Access to health services in the European Union', on effective ways of investing in health, received a lukewarm reception from the EAPM, which has submitted a document outlining what it believes is missing from the draft, or should be strengthened.

The Alliance filed an eight-page submission with dozens of key comments.

These begin with the concept of 'value', and EAPM's contention that those responsible for the provision of modern-day healthcare, in a Europe of 500 million potential patients across 28 Member States, should not consider financial concerns only as the basis for all discussion and progression.

Tom Van Der Wal, cancer patient survivor, a member of the Alliance, said: "There is a solid argument that value should always be defined in respect of the 'customer', Value in health care depends on results and outcomes – vital to the patient – regardless of the volume of services delivered, yet it appears that elsewhere the value is always going to be seen as relative to cost.

"For this and other reasons," he added "patients should always be involved at all levels on any discussions about what constitutes value. The Commission needs to understand this."

Read more [here](#)

SMART Outreach

EAPM gave a presentation in Romania on pancreatic cancer in early November. While the past decade has witnessed significant improvements in the survival rate of some cancers via huge progress in prevention, diagnosis and treatment, pancreatic cancer has resisted the trend.

The disease still has the poorest survival rates of any cancer and, according to predictions, pancreatic cancer-related deaths will keep rising across Europe, while that of other cancers will continue to fall.

There are several important research and medical unmet needs in relation to this disease, and the issues were discussed during the conference entitled 'Burning issues in Pancreatology' held on 6-7 November in Cluj-Napoca, Romania.

Pancreatic cancer is a hot topic at the moment, with the Alliance, in collaboration with the COST Action BM1204 EUPancreas, recently releasing a White Paper on the disease.

Most of the issues raised by the Alliance's paper were discussed in a meeting in the European Parliament earlier this month.

As a result of this, one EAPM member organisation, the European Cancer Patient Coalition, will take the lead with outreach initiatives in pancreatic cancer at the national level, supported by the Alliance at the political level.

The two-day conference in Cluj-Napoca, meanwhile, co-organised by EUPancreas COST Action, EFISDS and EPC, discussed how to renew efforts to develop more efficient prevention, diagnostic and treatment strategies.

The article the Alliance prepared on pancreatic cancer can be viewed [here](#)

Lung cancer White Paper launched

A White Paper aimed at tackling unnecessary deaths caused by lung cancer was launched on Tuesday, 10 November and aims to promote greater access to innovative treatment and more efficient organisation of research.

The paper states that lung cancer patients urgently need action at the highest level and is a direct appeal to EU and Member State policymakers, legislators and regulators.

EAPM writes that improvements will "depend primarily on greater collaboration between Member States and across the healthcare sector.



The collaboration should include patients, caregivers and patient organisations, who have an indispensable contribution to make”.

Lung cancer is the biggest global killer of all cancers. Fewer than half of newly diagnosed sufferers live beyond a year, with only 16% surviving for five years.

It is such a huge killer partly because it is harder to detect in its early stages. By the time a person begins to notice symptoms, it has often spread to other parts of the body and is, therefore, difficult to treat.

The majority of lung cancers in both sexes are caused by smoking, but about 15% are not, and the majority of those non-smokers are women, mostly young women.

Lung cancer in women has increased by a staggering 600% over the past 30 years. Today, more are killed each year by lung cancer than they are by breast, ovarian and uterine cancer combined.

Various theories have been posited for this (estrogen as a tumour promoter, is one example) but, put simply, scientists are just not sure. The Paper adds: “It is clear that physicians need more effective ways to detect and target these cancers.”

Read more [here](#)

Coming up...

On 14 December, the Alliance will hold an internal meeting to present an overview of activities to members, as well as the plans for next year. This will take place from 13-16.00.

During the morning of the same day (10-12.00), EAPM stakeholders will discuss ‘Disruptive Innovation: Launch of public consultation on preliminary opinion’. The intention is to draft a reply to this document from the European Commission’s Expert Panel.

The Commission says: “Disruptive Innovation is a type of innovation that creates new networks and players that tend

to displace existing structures and actors. It constitutes a real paradigm shift in the organisation of healthcare.

“(It) has the potential to reduce costs and complexity whilst simultaneously providing patients with improved access to healthcare resulting in better health and patient empowerment.”

The Commission’s preliminary opinion defines and classifies Disruptive Innovation, identifies drivers and barriers for its implementation, and assesses its relevance in the EU through case studies.

Our comments, and those of other stakeholders, will be reflected in the final opinion, which the Commission expects to see adopted by the end of February.

Education Summer School

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

The school will be held in Strasbourg, home of the European Parliament, and will run from 4-8 July.

Personalised medicine is, of course, 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.

To this end, the Alliance will bring 80 young professionals (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.

On top of this, examples of current and future personalised medicine approaches will be described and explained. These have been chosen to cover the majority of specialties, both on a clinical and biological side.



Data Protection trilogue

Data protection is currently being discussed in the 'trilogue' - the name for the discourse between the European Council, Commission and Parliament - in the run-up to the new Data Protection Regulation.

One of the sticking points of this upcoming ruling is that the European Parliament seems only to have focused on a blanket protection of personal data, without taking into account the myriad uses this vital information can have for research, especially in the world of medicine.

Parliament is undoubtedly acting with good intentions, but in this instance seems guilty of a knee-jerk reaction to fears over Google, Facebook and even the American government's ability to process and use data with what the public sees as little concern for the individual.

Researchers do not operate in such a slap-happy fashion and it is a total misconception that it is impossible to keep personal data safe, while still allowing its use for medical research purposes.

Data has been used in research for decades and the reasons for its storage have nothing to do with what the Parliament seems to fear. To throw medical data into a catch-all protective blanket is to completely miss the distinctions and, therefore, the whole point.

It is a fact that, whenever they can, researchers will ask consent before using personal data. But it is also true that sometimes consent is hard to get in practical terms. Imagine a study into, say, diabetes on a Europe-wide scale, and trying to contact hold of every person involved. Asking for individual consent to use their tissue or results would cause serious logistical problems.

So, should we throw away all this valuable data being

gathered now and much that has stored down the years, thus ignoring the needs of 500 million potential patients across 28 Member States? Of course not.

Trilogue discussions with the Parliament, Council and Commission began in June, with the aim of finding a compromise text. Informal agreement on the Regulation is not expected until the end of 2015, and formal agreement is expected in 2016.

Three articles concerning the General Data Protection Regulation are available below.

In the news...

EAPM has been busy penning articles and press releases for the media during November and below are a selection. Click on the title to go to the article.

[Health security is as vital as havens from terrorism](#)

[Focus group tackles better outcomes for EU cancer patients](#)

[Why all vital medical data cannot be anonymous](#)

[Lives are at stake in data protection talks](#)

[Data protection talks must make special case for research](#)

Taking Stock interviews

During recent weeks EAPM has been holding face-to-face interviews with stakeholders.

These include [Arturo Chiti](#), President of the European Association of Nuclear Medicine, [Anastassia Negrouk](#), Head of the International Policy Office at EORTC, [Ken Mastris](#), chairman of Europa Uomo, the European advocacy



movement for the fight against prostate cancer and [Brigitte Grube](#) (pictured above with EAPM Executive Director Denis Horgan), of the Danish Oncology Nursing Society, and Past President of EONS.

Also interviewed were [Roberto Salgado](#), a molecular pathologist who received his medical training at the University Hospital of Antwerp, Belgium, and the University Hospital in Leiden in The Netherlands, [Hendrik van Poppel](#), chairman of the Department of Urology at the University Hospital Gasthuisberg, Katholieke Universiteit Leuven, and [Ian Banks](#), president of the European Men's Health Forum since its launch in 2001.

Click on the names to read the interviews. More will follow in the coming weeks.

Twitter

EAPM is now active on Twitter.

You can find us [here](#)



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.

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



European Alliance for
Personalised Medicine