European Alliance for Personalised Medicine

High-level Conference

"Making Access to Personalised Medicine a Reality for Patients"

Monday 7 March, 10:00 to 17:30

Sala Napoleonica, Via Sant'Antonio 10, Milan

Guidance note for chairs and panelists

When: Monday, 7th March, 10:00 to 17:30

Where: Milan University, Sala Napoleonica, Via Sant'Antonio 10, Milan

Host: University of Milan, European Alliance for Personalised Medicine

Opening: Gianluca Vago, Rector, University of Milan

Mario Melazzini**,** President of Italian Medicine Agency (AIFA)

Beatrice Lorenzin, Italian Ministry of Health

Chairs: **Session 1**: Filippo de Braud, Director of Oncology Department, IRCCS; Gordon McVie, Kings College London, London, UK

Session 2: Gabriella Pravettoni, University of Milan; Mario Melazzini, President of Italian Drug Agency (AIFA)

Session 3: Pierfranco Conte, Professor at University of Padova

Panelists: **Session 1:** David Byrne (EAPM); Denis Horgan (EAPM); Gabriella Pravettoni, (University of Milan); Filippo de Braud, (IRCCS); Mark Lawler (Queens University, Belfast); Elmar Nimmesgern (European Commission); Gaetano Guglielmi (Ministry of Health, Roma); Giliberto Riggi (Astrazeneca Italy); Piergiuseppe Pelicci (IEO); Rob Hastings, Senior Manger, Market Development, Illumina; Fedro Peccatori, Scientific Director, European School of Oncology

Session 2 : Francesco De Lorenzo (ECPC) ; Mario Pazzagli (University of Florence) ; Paolo Casali (ESMO) ; Arturo Chiti (EANM)

Session 3 : Giovanni Martinelli ("L. and A. Seràgnoli" S. Orsola University Hospital) ; Angelo Paradiso, (NCRC, Istituto Tumori-IRCCS); Francesco Montorsi (Hospital of San Raffaele) ; Gianni Amunni (University of Florence)

Goal: To lay the foundation for a patient centered strategy involving Italian decision makers and regulators in the arena of public health, to enable EU and Italy to contribute to integrating Personalised Medicine into clinical practice while enabling much greater access for patients. To create the basis for the follow up on the Council conclusions for Personalised Medicine that were adopted by the 28 Health ministers in December 2015.

Participants: Public health decision makers, representatives from the Commission, Members of the European Parliament, patient organisations and umbrella organizations representing interest groups and associations actively engaged in the field of Personalised Medicine.

Contact: Ahead of the event, please feel free to contact the following people:

- Denis Horgan, EAPM Executive Director, Email: denishorgan@euapm.eu; Ph: 0032 472535104

BACKGROUND

We live in fast-changing times, with innovation occurring all around us. Few areas are seeing this more than the world of healthcare. Given ground breaking research, the emergence of so-called Big Data, advances in gene technologies and more, these are exciting days for medical science. Personalised medicine is coming greatly to the fore – the ability to give the right treatment to the right patient at the right time – while new developments in mHealth, telehealth and Smart wearables are delivering care outside hospitals. All of this leads to a healthier and wealthier society as patients spend less time in expensive hospital beds and doctors' surgeries while taking fewer days off work through illness. But to create a real environment in which personalised medicine can flourish, among other things, there needs to be an enabling of investment in innovation.

Making the best use of developments in healthcare is expensive and difficult. And these are tough economic times, which hardly helps matters. There are issues in respect of evaluation and approval at regulatory level – which can seem to take an age - while, on average, it takes more than 1 billion euro to develop an idea into a marketable, profitable product. On top of this, it takes from 10-15 years to get that product from bench to bedside. Valuable time for the patient, who could be benefiting from innovation much earlier.

The Alliance believes that the EU's law- and policy-makers must work to create an environment in which potential investors feel confident in, among other things, regulatory frameworks, the quality of research, talented innovators and a growing economy. We need these investors to financially support a healthy and wealthy continent, now and into the future. Put simply, better health for all means more productivity and an increase in growth, quite aside from our custodians' moral and ethical obligations to care for populations in the best way possible. There is an urgent need for an improvement in relationships between all key stakeholders in order to develop trust and new partnerships. It is vital that, for example, radiologists, urologists and clinicians can understand one another and devise a holistic response to any given treatment.

The conference aims to address the issue of the integration of Personalised Medicine into clinical practice and its compatibility with the principle of universal and equal access to high quality health care.

Following up on the reflections on the therapeutic benefits of innovation by the Italian Presidency in 2014, this event will set the scene for Council conclusions on Personalised Medicine to be adopted by the Health ministers during the Council of 8 December 2015.

SESSION FORMAT

The different sessions will take the form of a moderated discussion, featuring experts from different governments, sectors and areas. The stage will be set up in a sitting "talk show" format. As the conference aims to encourage a dynamic and open exchange, powerpoint presentations should possibly be avoided.

The moderator will announce the different sessions, introduce the chairs and ensure the transition from each session to another or to breaks.

The chair will briefly introduce the panelists and frame of the topic of the session after which the panelists will immediately engage in an open discussion. Each speaker should focus on one specific item related to the session topic. He/she will be answering targeted questions addressed by the chair. Answers should be concise and to the point, so that it allows the chair to raise follow up questions and/or ask the other panelists to react to the statements made by their colleagues. Approximately 50 minutes will consist of a conversation guided by the chair, with the remaining 20 minutes consisting of a questions and answer session allowing the audience to participate in the discussions. At the end of the panel, the chair will ask each panelist to address one key message to decision makers on his/her topic.

The link between the panel and the audience will be done by the moderator who will take questions from the floor.

Panellists are encouraged to adopt a conversational tone, share anecdotes, best practices and examples, where appropriate.

PANELLISTS – ISSUES ADDRESSED

Objective 1: *For Personalised Medicine to succeed and for healthcare innovations to fulfil their true potential, an informed, engaged and empowered patient is crucial. Personalised Medicine often calls for an enhanced need of information and advice. This session looks at patients concerns, expectations and priorities with regard to Personalised Medicine and to have a coherent approach.*

- Patient empowerment
- Shared decision making
- Informed consent – communication
- Patient focused care
- Data sharing – data protection

Objective II: *To put Personalised Medical into the wider context of public health policies and outcome centered approaches as well as to give an insight into the Commission's further plans in this field.*

- PM and Public Health Research
- PM and Public Health Policy
- PM and EU Health Policy
- Putting PM into perspective: the USA precision medicine initiative

Objective III: To address the following issues from the Italian perspective

- Adjusting Health Technology Assessment / HTA methods to the value of Personalised Medicine
- Safe and timely access to medicine / adaptive pathways
- Training of healthcare professionals : continuous professional development
- Setting up of European reference networks : biobanking networks
- Paying for Personalised Medicine

Brief guidance for the Preparation of the session

EAPM would like to invite the Chair to structure the discussion together with the speakers on the panel - and the subsequent Q&A session with the audience - around the questions below to ensure concrete, clear, usable and "marketable" answers/recommendations in session to feed into tangible action at the national level

Choreography of the Session

Moderator presents the session and introduces the chair. Panelists and chair take their chairs.
Chair introduces the panelists. He reminds panelists that their answers should short and concise (approximately 3 to 5 min).
Panel discussion Each panelist intervenes for max 8 minutes on the question of the chair. The chair may engage panelists on the topics of other panelists to create interactive discussions. Brief transitions between the different topics are done by the chair.
Chair opens the floor for questions. Chair reminds audience that questions are short and directed to one panelist.
End of session: Chair asks each panelist to give his key political message to the decision makers on national, EU and international level.

Structure of the Discussion

EAPM would like to invite the chair and the speakers to focus on the following ***indicative*** questions :

1. ***What we would like to know:"PM and Public Health Research":***

   - How must Public Health Research be structured/focused in future to best foster PM with the patient at its center?
   - Can we draw any lessons learned – and if yes, which ones – from former research projects on PM?
   - Which research tools should be (more) relied on in future to increase awareness and knowledge in Public Health Research on the benefits of PM for patients?
   - Are there regulatory hurdles that need to be softened to foster public health research in PM?

2. ***What we would like to know "PM and Public Health Policy":***
   - Why is there a gap between public health research outcome and the application/implementation of these outcomes in Public Health Policy (and medical practice)?
   - How can we bridge this gap?
   - How should we involve patients in decision making process in Public Health Policy on PM?
   - Which policy tools should be (more) relied on in future to increase awareness and knowledge on the benefits of PM for patients?

3. ***What we would like to know "PM and EU Health Policy":***
   - Is there a robust EU legal and political framework for PM which meets current and future challenges?
   - What role should the patient play in EU Health Policy on PM?
   - Is there a need for a (more streamlined) common political PM approach at EU level? Or do we even need a proper EU strategy on PM?

4. ***What we would like to know:***

   - Is there a difference of approaching PM in the Italy in comparison to the EU/MS? If yes, which one and why is there a difference?
   - Is there a need – and if yes, a way - for both sides of the Atlantic to closer cooperate on PM?
   - Can the MS and the EU contribute to strengthening awareness of PM and cooperation to implement PM for the benefits of patients worldwide – and if yes, what would be the specific added value that MS and the EU could contribute at international level?

5. ***Patient empowerment"***

   What is concretely needed to empower patients in Personalised medicine? Which measures should be applied?
   - Does patient empowerment in the field of Personalised medicine need to be adjusted to this specific strain of medicine and/or to specific patient needs?

6. ***"Data sharing – data protection***

   - How can we ensure a right balance between the circulation and sharing of personal health data on the one hand and the respect of individual rights to data privacy on the other hand?
   - How to make sure that patients' consent to the processing of those personal data respects their privacy?
   - What to expect from the regulation on data protection?
   - Would the right of Member States to maintain or introduce more specific provisions with regard to genetic data or health data, as provided in the current version of the regulation, always be in the interest of patients?

7. ***"Shared decision making"***

- What concrete measures need to be taken by decision makers to ensure shared decision making in the field of PM?
- What is the role of good information flows and efficient communication pathways, supported by an optimised health literacy of populations?
- How can we ensure that PM is inclusive? How can PM address disadvantaged or elderly patients?
- What is expected in terms of education from health care professionals to meet patient's health literacy needs?
-

8. ***"Informed consent – communication"***

- How to make sure informed consent forms are informative and understandable by patients?
- What models to choose for patient consent in 'merged' clinical and research learning? Solutions need to be "creative, practical and respectful".
- Is it necessary to review current practices in patient consent and in waivers to consent?
- How to reach a common understanding about mechanisms that are privacy protective?
- What are the benefits of involving patients more in clinical trial modelling?

9. ***"Patient focused care"***

- Does PM entail specific requirements in terms of patient focused care?
- How can patients and patient organisations be better involved in the discussion on patient focused care?
- How to ensure that PM care is respectful of and responsive to individual patient preferences, needs, and values, and ensuring that patient values guide all clinical decisions?
- Is it realistic to expect better health outcomes from active involvement of patients and their families in the design of new care models?

Please do not hesitate to contact us in case of any further questions.
Denis Horgan, EAPM Executive Director, Email: denishorgan@euapm.eu; Ph: 0032 472535104

We look forward to good cooperation with you and a fruitful conference