**TEACH Summer School**
*Cascais, Portugal*
*3-7 July, 2016*


# *Training and Education for Advanced Clinicians and HCPs in Personalised Medicine Report 2016*

European Alliance for Personalised Medicine

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## Introduction

The Brussels-based European Alliance for Personalised medicine (EAPM) held its first TEACH Summer School in Cascais, Portugal, from 3-7 July, on "How to communicate to patients on personalised medicine".

TEACH stands for Training and Education for Advanced Clinicians and Healthcare professionals (HCPs), and was aimed at young professionals aged 25-40.

Attendees from more than 20 countries (including the UK, as well as Germany, Netherlands, Italy, France, Bulgaria, Spain and more) gathered at the Cultural Centre in Cascais, and the faculty put in place by EAPM and its stakeholders also had a similar EU-wide spread.

The event was highly interactive, with much communication among the broad mix of attendees (general practioners, urologists, oncologists, biologists, pathologists, biobanking, patient organisations, patient communication experts) and also between attendees and the faculty. It contained auditorium plenary sessions on various topics on personalised medicine, communication tools and health literacy, with added interactive round tables to the mix, as well as role-play sessions, and social events with talks.

The event's sponsors were EFPIA (the European Federation of Pharmaceutical Industries and Associations), the European Hematology Association, and genetic giants Illumina.

Other organisations involved in the event were:

- European Society for Nuclear Medicine
- European Association of Urology
- European Respiratory Society
- European Society of Pathology
- European Society of Pharmacogenomics
- European Institute for Oncology
- Association of Public Health School
- European Brain Council
- European Association of Hospital Pharmacists
- European Organisation for the Research and Treatment of Cancer
- European Society of Medical Oncology

Topics and specialised areas on personal medicine covered across the week included respiratory diseases, oncology, urology, hemathology, pathology, imaging, cardiology, use of monoclonal bodies for diseases and imaging and pathology, inhibitory drugs, pharmacogenomics and biobanking. These were chosen to cover the majority of specialties, both on a clinical and biological side that may at some time be required to explain to a patient.

Essentially, if personalised medicine is to be in line with the EU and Member State principle of universal and equal access to high quality healthcare, then clearly it must be made available to many more citizens than it is now. Part of what is required is a long-term approach to education to ensure the translation of new therapies from laboratories to patients.

This means that 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.

This inaugural summer school recognised that the patient is at the centre of his or her own treatment and health-related decisions, and focused heavily on training in "how to communicate with patients" in several key areas. The school will be followed-up by several webinars.

EAPM is convinced that an improvement in skills among HCPs is vital to giving the right treatment to the right patient at the right time.

On the later pages are just a selection of the presentations across the duration of the school, using key points.

***Christine Chomienne**, Past President, EHA*
***Louis Denis**, Director Wij Ook/US TOO Belgium*
***Denis Horgan**, Executie Director, EAPM*

*Summer School Co-Chairs*

# TEACH Summer School

## *Perspectives from speakers and delegates*


*"The summer school has been really interesting and constructive. We came together from so many places, different professions. It was very constructive guiding us into future direction.s"*

*Sebastian Fussek*
*Rasboudume Nijmegen, Department of Urology*


*"The general feeling from all of us was that it was very well done, it was nicely organised. The topics were current. The speakers were excellent. This was the first summer school and overall it was a great experience and we enjoyed it.*

*Jelena Spasic*
*Institute for Oncology and Radiology of Serbia*


*"At the summer school I learnt a lot myself and also about my own profession in the context of the other professions. It has given me inspiration actually to work in this field. As a pharmacist I work with oncology so I learnt more about that."*

*Frank Jorgensen*
*Haukeland Hospital Pharmacy*


*"I really enjoyed being here and I really enjoyed meeting so wonderful people and from different parts of the world. Yes it was really wonderful."*

*Katharina Ocko*
*Allgemeines Krankenhaus Wien*


*"It was a very productive roundtable discussion on actually what is personalised medicine and is it going to go in the future and what can we all conatribute to that? It's going to be the future."*

*Mark Behrendt*
*Netherlands Cancer Institute (NKI)*


*"There are a lot of physicians here and also a lot of people from other areas and I think it is really important for us to meet and to speak and exchange ideas so that we can learn how to communicate, collaborate, do some research together."*

*Sarah Redensek*
*University of Ljubljana*

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## *Perspectives from speakers and delegates*

*"We need to educate patients, but we need to use plain language. If we do that it will make it easier for patients to communicate with doctors, but doctors need to understand they need to accept questions and they need to be prepared to answer those questions properly."*

*Natacha Bolaños*
*Spanish Group for Cancer Patients, GEPAC*

*"Only on the basis of correct, updated, repetitive, repeatable and reliable information can you plan a decision together with your treating doctor."*

*Louis Denis*
*Wij Ook/US TOO Belgium*

*"It was nice to see some young and up and coming stars at the summer school and I think that the younger generation will have a different view on treatment of patients. I think the dialogue between the physician and the patient will change in the future."*

*Ken Mastris*
*President, Europa Uomo*

*"I expected the Summer School to be good, but it was better than I anticipated - the attendees were from many different countries and different specialities, very trans-disciplinary, very European."*

*Christine Chomienne*
*Past President, EHA*

Training and Education for Advanced Clinicians and HCPs

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## Presentations

On the following pages are a selection of (using key points from) the presentations across the duration of the school.

Other presentations were delivered by: **Steve Johnson**, *Taunton UK*; **Ricardo Bapista**, *MP, Portuguese Parliament;* **Angelo Paradiso**, *IRCCS Foundation - Istituto Tumori Bari;* **Philippe Rousselot**, *Service d'hématologie et oncologie, CH de Versailles;* **Luis Mendao**, *Chair of the Board of GAT - Treatment Activist Group;* **Giovanni Codacci Pisanelli**, *Assistant Professor of Medical Oncology, Rome University*; **Rob Hastings**, *Senior Manager, Market Development, Illuminan and;* **Ken Mastris**, *President, Europa Uomo.*

***Natacha Bolanos***
***Spanish Group for Cancer Patients, GEPAC***

***Silvia Riva***
***University of Milan, Faculty of Oncology and Hemato-oncology***

These presentations gave an overview stating that in the field of psychology, over the past few decades, health literacy has been recognised as a critical determinant of successful or unsuccessful disease management in which the patient assumes an important role.

More than in the past, people want to be involved in making decisions about their preferences in terms of care and treatment. Although physicians have historically been the direct voice of health and medical information, other voices are becoming more accessible to the general population with the rapid diffusion of health information via media, internet, and other social networks.

Thus, patients' skills in applying information and making judgments about health preferences may have a critical impact on their health.

According to the World Health Organization, health literacy is defined as: "The cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health".

In recent years, health literacy has begun to be explored at a European level showing a number of differences across countries. This is an important aspect for orienting actions and promoting prevention and knowledge in the prospective of personalisation of care at the European level.

Policy makers' in health literacy should work together with researchers in health literacy, not only to further investigate the processes but also to create effective opportunities to improve health literacy in all patients and to promote better decisions in all health contexts taking into account differences and characteristics of different countries and supporting a tailored and personalised approach of healthcare management.

Health information is often inaccessible because the literacy demands of health systems and the literacy skills of average adults are mismatched.

Low health literacy has a negative impact on a patient's health status and use of the health care system. Patients with low health literacy levels cannot make decisions regarding their health care or follow instructions on medications and health maintenance behaviours. It is the health care provider's responsibility to ensure that patients with low health literacy levels are identified and measures are taken to ensure those patients understand their options and instructions.

To educate these patients, health care providers need to develop resources that are easily understood and interview skills that can ensure patient comprehension.

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***Peter Kapitein***
***Founder of Inspire2Live***

Peter said we can get cancer under control by the cooperation of patients, researchers and clinicians and with the combination of emotions and arguments. 'Emotions', because there are patients that are dying and need better treatments. 'Arguments', because we can only cooperate when patient advocates know everything about the way the researchers and clinicians work and are an equal partner in this fight.

We know how to do the things that will benefit the patient, we want to do these things and we can do it. So what is preventing us from doing it? Yes, there are barriers like data, law and regulation, money, privacy and of course the publication culture that determines the reward structure; publish or perish. But there is more.

The way the medical industrial complex works has great similarities with the financial and military industrial complexes. The way the academic world works together with government and industry does not necessarily benefit patients and their loved ones. Similarly in the financial industrial complex the citizens and owner of saving accounts also see that their interest is not always served in a proper way.

I stopped believing that there is bad intention in all this. There is not. It is my conviction that we've lost the possibility of having good discussions about good and bad. We do not challenge each other any more. When we have good discussions then the outcome determines the rules and regulations that we want to follow.

It should be morality that defines the law, but it is now the law that defines morality. The cause of this is the stopping of thinking: 'The sad truth about evil is that it is been done by people who never make their minds up about good and bad' (said Hannah Arendt). This is why a doctor is honest and thinks he or she is doing the right thing when telling a dying patient that he or she can't give this drug because she does not know what the long-term effects of this drug are.

In reality, the patient would have been very happy with long-term effects after five years.

Now, we can bring back the right order of morality and law by four rules:

- Put different people in a room
- Go for the root cause
- Scale up fast
- Be independent

By doing this in the cooperation between patients, researchers and clinicians and using the emotions and arguments to define the why, what and how, we are able to get cancer under control and inspire people to lead happy and healthy lives in harmony with cancer.

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***Peter Riegman***
***Head of the Erasmus MC Tissue Bank, The Netherlands***

Peter explained that biobanks are developed in relation to a research question having its own strategy and specific demands on quality and annotation of the collected samples, resulting in a very heterogeneous concept.

Even considering exclusively human samples-related banks for research, there are multiple designs according to the different possible goals. In a brief summary, human-driven biobanks include three mayor types:

i) Population banks. Their primary goal is to obtain biomarkers of susceptibility and population identity, with germinal-line DNA from a huge number of healthy donors, representative of a concrete country/region or ethnic cohort.

ii) Disease-oriented banks for epidemiology. Their activity is focused on biomarkers of exposure, using a huge number of samples, usually following a healthy exposed cohort/ case–control design, and studying germinal-line DNA or serum markers and a great amount of specifically designed and collected data.

iii) Disease-oriented general biobanks (i.e. tumour banks). Their goals correspond to biomarkers of disease through prospective and/or retrospective collections of tumour and no-tumour samples and their derivates, usually associated to clinical data and sometimes associated to clinical trials.

Those data are usually not collected for a concrete research project, except in case of clinical trials, but from the healthcare clinical records.

A variety of access rules are found between biobanks, dependent strongly on the embedding of the biobank and the relation with the stakeholders. The access rules differ too much on one point to become completely harmonised. The main stakeholders in a population bank are the donors and the biobank with a committed research team, whereas in clinical biobanks the clinicians and a variety of researchers also belong to the stakeholders.

Without the cooperation of the clinicians there will be no collection at all. Therefore, this group needs to be involved on the decisions to issue collected samples to other requesting parties and this process needs to be repeated for all incoming requests, either from within the institute, or from external parties.

***Torsten Haferlach***
***MLL Münchner Leukämielabor***

The diagnosis in hematology has been revolutionised in the last ten years and will still be much more granulated in the next ten years.

As we still start from cytomorphology and standard cytogenetics including also immunophenotypic approaches, the molecular field has emerged dramatically.

This is possible due to new sequencing techniques such as Next-Generation-Sequencing, quicker turn-around time and cheaper assays.

In hematology, we can investigate peripheral blood and bone marrow cells from the respective patient. This makes it easier to apply all these techniques in parallel.

New markers and genes that have been deciphered in the last ten years by these new sequencing approaches that have unravelled the pathobiology in many of the hematological diseases.

This improves the diagnostic approach, the classification, the prognostic information as well as targeted treatment strategies.

With respect to personalised medicine, the use of molecular information is mandatory.

Thus, a broad approach to diagnosis in hematological diseases paves the way to a comprehensive diagnosis, classification and especially opens the field for new drugs, targeted treatment approaches, minimal residual disease studies and individualised therapy.


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***Ron Schaik***
***Full Professor of Pharmacogenomics and President of ESPT***

Ron explained that pharmacogenomics is the science of genetic influence on an individual's responses to medication. It has the potential to optimise both drug development and drug therapy decision-making via enhancing the efficiency of clinical trials of new drugs and targeting medicines in clinical practice for improved health and economic outcomes.

Research that underpins this science has focused on common genetic variations, including single nucleotide polymorphisms (SNPs), genomic insertions and deletions, and genetic copy number variations (CNVs). SNPs appear to be the most frequently inherited sequence variations, but CNVs account for larger regions of the genome.

It is not clear which is more crucial in pharmacogenomics, but it is likely that both play a role in the phenotypic outcomes and parameters. Research has shown that variations in genes contribute to an individual's drug sensitivity, resistance and toxicity.

Clinical practice boasts an increasing number of promising examples of pharmacogenomic tests, with most being applied in specialty care such as oncology. However, there has been little integration into primary care due to the complexity of the fundamental science, as well as clinical, economic and organisational obstacles to the effective delivery of the medicine.

Oncology is, and potentially will continue to be, the most promising field in pharmacogenomics since tumoural genetic variability is far more significant than that of our constitutional genome, multiplying the situations in which a response to a drug might be genetically determined. Also, in cancer therapeutics, there is a constant influx of novel targeted anticancer drugs released on the market since new technologies facilitate an exponential discovery of potent new tumoural drug targets.

The public health benefit of using pharmacogenomics to improve the risk-benefit profile of new and existing drugs is potentially significant. Pharmacogenomic testing has been shown to be cost-effective for therapies that are expensive, possess significant risks of serious adverse events, or for drugs that have a poor or highly variable drug response.

**Gianpiero Cavalleri**
**Royal College of Surgeons in Ireland**

Gianpiero explained that epilepsy affects 50 million persons worldwide, a third of whom continue to experience debilitating seizures despite optimum anti-epileptic drug (AED) treatment.

Twelve-month remission from seizures is less likely in female patients, individuals aged 11-36 years and those with neurological insults and shorter time between first seizure and starting treatment.

He said that there is a clear unmet need in terms of the clinical management of patients with drug resistance. It is likely that there is more than one mechanism, and using disease stratification procedures, including examining the role of inflammation, will lead to disease subphenotypes, which may stimulate novel therapeutic approaches including the development of new drug–diagnostic combination products.

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***Holger Moch***
***University Hospital Zurich, Department of Pathology, Switzerland; European Society of Pathology***

Holger explained that pathology can described as the study of the essential nature of diseases and especially of the structural and functional changes produced by them.

Personalised medicine is revolutionising the way doctors diagnose, characterise and treat cancer, for example, and pathologists can make major contributions to dramatically improving the care of their patients.

Yet change is required as pathologists need to be the experts in the medical system and must embrace personalised medicine. Emerging technologies are a critical advance as, for the first time, pathologists can generate genomic profiles of patients' tumours that incorporate histologic pattern information.

Meanwhile, pathology-training programmes must change to ensure that pathologists are aware of developments taking place in the field.

As we know, personalised medicine relies on new methods of genetic-based analysis to determine a patient's susceptibility towards certain diseases, and probably their reaction to any given treatment.

Pathologists are invaluable when, for example, it comes to companion diagnostics, being very familiar with tests and the reporting of test results to front-line clinicians.

Nowadays, they no longer only perform tests and interpret the test results, but are directly involved in improving efficiency and quality of care. Pathologists and laboratory professionals are today very-much involved in developing guidelines for appropriate use of lab tests as well as advanced laboratory diagnostics.

They have a key role to play in delivering care that is personally tailored, efficacious, and cost efficient.

***Ian Adcock***
***Professor of Respiratory Cell & Molecular Biology and Head of the Molecular Cell Biology Group, Imperial College***

Ian said that, in this age of personalised medicine and emerging technologies it is clear that a major issue in managing respiratory diseases is the fact that certain subsets of patients do not respond well, if at all, to available treatments. It should be the case that clinicians can access diagnostic markers in order to personalise drugs for their patients' use even before treatment gets under way.

Genes may change in expression in diseases such as asthma and chronic obstructive pulmonary disease. Asthma is a condition in which airways narrow, swell and produce extra mucus. This can make breathing difficult and bring about coughing, wheezing and shortness of breath.

At the moment, asthma can't be cured, but its symptoms can be controlled.

Despite advances in personalised medicine, single biomarkers may not be enough to stratify patients properly, and it seems that a change of scale to omics-based diagnostics may be necessary.

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So how can we make this work? It comes in three areas:

- Measurement and validation of human genes, gene products, and metabolites
- Extraction of genome-wide data with diagnostic value, based on understanding ofr targeted omics
- Biomarkers being clinically useful at reasonable prices

But, still, many challenges need to be addressed:

- Clinical research is needed to determine and validate what targeted omics analyses are needed for diagnosis.
- Laboratory technology for targeted omics must be developed in clinical settings.
- Software is needed for diagnostic classification based on the omics data.

As we learn more about how patients do or don't respond to treatments, this could lead to pharmaceutical companies developing new drugs for non-responders. If we can overcome the challenges outlined then multiple novel therapeutic options could be used to treat respiratory diseases. New diagnostics could properly personalise options down the line.

James Spicier — Senior lecturer in the Cancer Studies Division of King's College London

James explained that monoclonal antibody-based treatment of cancer has been established as one of the most successful therapeutic strategies for both hematologic malignancies and solid tumours in the last 20 years.

The initial combining of serological techniques for cancer cell surface antigen discovery with hybridoma technology led to a series of landmark clinical trials that paved the way for new generation antibodies and subsequent clinical success.

The use of monoclonal antibodies for the therapy of cancer is one of the major contributions of tumour immunology to cancer patients. This success is built on decades of scientific research aimed at serological characterisation of cancer cells, techniques for generating optimsed antibodies to tumour targets, detailed investigation of signalling pathways relevant to cancer cells, and an understanding of the complex inter-play between cancer cells and the immune system.

The clinical development of antibodies is inextricably linked to disciplined and detailed exploration of the properties of antibodies in vivo and assessment of functional effects on cancer cells. One of the major challenges is now to fully exploit antibody therapies in cancer patients by combining the two major immune-based treatment approaches - antibodies and vaccines.

Trials combining ipilimumab with vaccines have shown mixed results thus far. The Cancer Vaccine Collaborative, a joint academic clinical trials infrastructure established by LICR and the Cancer Research Institute, is about to embark on a series of trials exploring NY-ESO-1 vaccines along with ipilimumab to further investigate this important area.

In this way, the full promise of tumour immunology in controlling and treating cancer will hopefully be realised.

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***Paolo Casali***
***ESMO***

Paolo explained that knowledge gaps about the causes and clinical progression of a given rare disease make it difficult to determine the best strategy for targeting the condition and compound the inherent complexities of developing medicines.

For example, clinical trials are an important part of the drug development process, but a lack of understanding of a disease can make it difficult to design and conduct clinical trials. Furthermore, the small patient populations in rare diseases often make it difficult to recruit a sufficient number of patients to participate in clinical trials and gain statistically significant results.

This issue is particularly problematic when trying to address rare diseases that have a significant impact on children, given that children comprise an even smaller percentage of the overall population.

Yet, despite remarkable progress, only 5% of rare diseases today currently have available treatment options and much work remains. A recent PhRMA report found there are currently more than 450 orphan drugs in development, offering patients more hope than ever before.

A major area of this research targets rare cancers, accounting for more than one-third of all rare disease medicines in development. Other top research areas for rare diseases include genetic disorders, neurological conditions, infectious diseases, and autoimmune disorders.

A decade ago, the treatment of CML had been dramatically transformed by a new class of medicines known as tyrosine kinase inhibitors (TKIs). TKIs are targeted therapies developed to treat cancer at the cellular level by affecting biologic pathways specific to cancerous cells. Imatinib was the first TKI to be approved by the FDA in 2001 and was the result of decades of research seeking to uncover the biological mechanisms associated with the "Philadelphia Chromosome"— an abnormality in chromosome 22 found in 95% of CML patients.

Today, an arsenal of additional targeted therapies is available for patients with CML, many of which are particularly effective in instances where mutations may have rendered imatinib ineffective.

CML patients are living close to normal life spans thanks in large part to a greater understanding of the biological basis of this disease and continued development of targeted therapies to treat it.

Philippe Rousselot (Hospital Versailles Paris) and Torsten Haferlach (MLL, Munich) highlighted respectively how pharmacokinetic and future pharmacogenomics data will allow to give the right dose of TK inhibitors in CML patients for best prolonged efficacy and less side effects and how current and future high future genomics will allow to tailor patient diagnose and prolonged response.

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***Conclusions***

The ground-breaking summer school was centred around the concept of personalised medicine, which refers to innovative medical interventions tailored to the specific needs of individual patients, thus providing better treatment and preventing undesirable adverse reactions while fostering a more efficient and cost-effective healthcare system, and how to communicate with patients on the topic of personalised medicine

Among other aspects, the summer school was designed to provide a forum for presenting new data from clinical trials and basic research and sharing ideas for innovation.

It allowed its attendees to enhance their knowledge of evidence-based approaches on diagnosis and treatment, let them access the latest results on clinical and translational research, and brought them up-to-speed on emerging innovative techniques, diagnostic tools and more.

In the changing world of health care in Europe, the education of health care professionals is under-emphasised.

The true potential of all of this fantastic new science, built around genetic profiling and individual DNA, will never be fully realised unless front-line clinicians have the knowledge and understanding to exploit it.

HCP/patient relationships will be key. One key goal is giving clinicians better tools to treat and inform their patients and allow HCPs a better understanding of their patients' needs.

The issue of education of HCPs 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.

Europe must ensure that no patient is denied a suitable treatment due to a lack of knowledge or understanding on behalf of the HCP treating and diagnosing him or her.

Personalised medicine starts with the patient. It holds huge potential for improving the health of many patients and ensuring better outcomes of health systems' efficiency and transparency.

Yet, its integration into clinical practice and daily care is proving difficult given the many barriers and challenges to timely access to targeted healthcare that still exist as of today.

If personalised medicine is to be in line with the EU and Member State principle of universal and equal access to high quality healthcare, then clearly it must be made available to many more citizens than it is now.

Part of what is required is a long-term approach to education to ensure the translation of new therapies from laboratories to patients.

This means that 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.

This inaugural summer school aimed to support the endeavours of EAPM to set up a Continuous Educational Programme on personalised medicine.

Recognising that the patient is at the centre of his or her own treatment and health-related decisions, the summer school focused heavily on training in "how to communicate with patients" in several key areas.

EAPM and the faculty at this first summer school are convinced that an improvement in such skills among HCPs is vital to giving the right treatment to the right patient at the right time.

# European Alliance for 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.**


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