

# PAYING FOR PERSONALIZED MEDICINE AND IMPLEMENTATION IN PATIENT CARE

## November, 13 2014

### THEMATIC Sessions

#### SESSION I: Welcome by the conference chair (09:00-9:30)

<b>Maarten IJzerman</b> , University of Twente, The Netherlands	Introducing the third Health Economics & Personalized medicine symposium: paying for personalized medicine
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#### SESSION II: Paying for Personalized Medicine (9.30-11:00)

According to a recent report of the Food and Drug Administration, personalized medicine has clearly arrived in the regulatory space. Of all drugs approved since 2011 by the Center for Drug Evaluation and Research (CDER), about one-third had some type of genetic or other biomarker data included in the submission to characterize efficacy, safety or pharmacokinetics. Meanwhile, discussions are going on about the rising costs of biologicals in oncology and measures to control spending. For instance, a recent report of the cancer foundation KWF in the Netherlands suggests to introduce a cost-effectiveness threshold. In this session, we will illustrate different perspectives from other countries and intend to stimulate interaction among the panelists.

Moderator	<b>Uwe Siebert*</b> , UMIT, Hall and ONCOTYROL, Innsbruck, Austria
<b>Adrian Towse</b> Office Health Economics, London, UK	Challenges in the development and reimbursement of personalized medicine
<b>Mondher Toumi</b> , University Lyon, France	Policy Perspective on Market Authorization and Evidence Development for Personalized Medicine in France
<b>Meriem Bousloul</b> , Gemeinsamer Bundesausschuss, Berlin, Germany	G-BA perspective on access to innovative oncology drugs – Experience with the early benefit assessment of pharmaceuticals
<b>Lou Garrison</b> , University of Washington, USA	Personalized Medicine: Pricing and Reimbursement Policies as a Potential Barrier to Development and Adoption

### COFFEE BREAK (11.00-11.30)

#### SESSION III: MODERATED PANEL SESSION (11.30-12.30)

Various aspects in the introduction of personalized medicine (PM) are still in development and can shape the diffusion scenarios for various diseases and treatments. For the cancer field, this ranges from (lack of) consensus on the exact choice and number of panel genes to preparedness of payers to cover off-label drugs resulting from sequencing on “omics” related analysis. The macro impact of these developments in Personal Medicine on healthcare costs is not clear; the costs of diagnostics is reducing fast leading to sharp selection of therapeutic subgroups, whereas the new prices of pharmaceutical products are sky-high. It is thus unclear what its effect on the total expenditure growth will be. As input for the panel session, some issues like projected cost development, possible cost-savings and implementation in national health systems will be dealt with.

Moderator	<b>Wim van Harten</b> , Organization of European Cancer Institutes, Brussels, Belgium, Netherlands Cancer Institute Amsterdam
<b>Panelists</b>	Koos van der Hoeven, LUMC, Leiden, The Netherlands Adrian Towse, Office Health Economics, London, UK Mara Aspinall, former CEO Ventana Inc., USA Peter Kapitein, Inspire to Live, patient representative

### NETWORKING AND LUNCH (1230-1330)

### SESSION IV: Stakeholder perspectives in the implementation of personalized medicine (13.30-15:00)

Today's healthcare is –to a large extent- guideline based. The promise of PM is that more individual services can be provided, thereby improving access to healthcare, quality of care and efficiency. The implementation of personalized medicine to a large extent is based on perspectives of various stakeholders involved in decision making. However, different stakeholders perceive value of personalized medicine differently. This session will introduce some of these perspectives and will also discuss the implications for evidence generation and policy. Both, a clinical and patient perspective will be provided and illustrated by the implementation of molecular profiling in breast cancer and the uptake of biosimilars in oncology.

<b>Moderator</b>	<b>Andrea Manca</b> , University of York
<b>Sabine Linn</b> , Netherlands Cancer Institute, The Netherlands	Implementing personalized medicine in patient care: a clinical perspective
<b>Deborah Marshall</b> , University of Calgary, Canada	Using Preference Methods to Measure the Value of Personalized Medicine from Multiple Perspectives- Tradeoffs at the Bench and the Bedside
<b>Brett Hauber, PhD</b> RTI health solutions, Research Triangle Park, USA	Elicitation of stakeholder preferences to estimate adherence and adoption of personalized drug treatment
<b>Dennis Raisch, PhD</b> University New Mexico, Albuquerque and University of Twente, Netherlands	Biosimilar drugs in oncology: A stakeholder perspective to determine preferences for collecting post-marketing data for biosimilars

### COFFEE BREAK (15.00-15.30)

### SESSION IV – EPEMED session: Personalized medicine in Europe in 2014 – what are the remaining hurdles ? Do patients have real access to innovations ? (15.30 – 17:00)

EPEMED with La Charite in Berlin have identified gaps, deficiencies and remaining hurdles in terms of HTA evaluation, pricing, reimbursement and distribution of personalized medicine innovations in the major EU countries. EPEMED proposes recommendations based on expert opinion on what should be the way forward for a complete assessment and economic evaluation of personalized medicines. And in practice how does it work and translate to European patients? How public initiatives are accelerating adoption of personalized medicines among clinicians? What kind of financing schemes are available? What is the impact on PM and CDx manufacturers? How their contribution is going to accelerate adoption?

Decipher and meet the access challenges to a better health for European patients also mean educate stakeholders on the breakthrough role of personalized medicine and diagnostics. Disseminating the latest information on personalized medicine worldwide is therefore of first importance. Are other countries ahead in terms of innovation / research / implementation?

EPEMED and DXInsights in the USA are currently developing the most important knowledge data center in personalized medicine: this initiative will also be presented during this session that concludes with an interactive discussion panel.

Introduction and Moderator	<b>Alain Huriez</b> , Chairman EPEMED, the European Personalized Medicine association, Luxembourg
<b>Iain Miller</b> Founder Healthcare Strategies Group <b>Pablo Jordan</b> GSK Head of diagnostics partnering	Best Practices and Emerging Trends for Market Access to Personalised Medicine in the US and EU. Conclusions and final recommendations from the EPEMED La Charite study together with the US perspective.
<b>Guido Brink</b> Vice President Regulatory Affairs & EU Market Access, Agendia	Regulatory and market access hurdles in Europe for Molecular diagnostics biomarkers: the practical experience of a personalized Medicine European leader
<b>Angelo Paci</b> , Institut Gustave Roussy France	At the clinician level: practical aspects of PM implementation. Financing the access to innovation
<b>Werner Verbiest</b> , Global Head Janssen Diagnostics	Experiences and perspectives from a PM/CDx Industry Player

**Mara Aspinall**, former Ventana CEO,  
Founder, International School of  
Biomedical Diagnostics  
**Sander Brinkhof**, MSc, University of  
Twente

Educating stakeholders on the importance of PM– global initiative of knowledge data center:  
The joined EPEMED-DxInsights 2014-2015 initiative.

**RECEPTION (17.00-18.00)**