PROGRAM

2nd ANNUAL HEALTH ECONOMICS & PERSONALIZED MEDICINE SYMPOSIUM

LUXEMBOURG, 28-29 OCTOBER 2013

DEVELOPING A COMMON FRAMEWORK FOR CLINICAL & ECONOMIC EVIDENCE

Symposium Overview: Personalized medicine technologies offer the promise of tailored risk assessment, diagnosis and treatment, yet despite significant investment in development of such technologies, relatively few have been successfully translated into clinical practice for the benefit of patients. This symposium will examine the pathway for development of personalized medicine technologies, from research and development, technical and validation studies, regulatory environment, and market access hurdles in Europe, with the goal of developing a common framework for the development of clinical and economic evidence required to bring such technologies to patient care. The goal of the symposium is to lay out a roadmap for technology development, with special emphasis on value considerations and the use of economic evaluation encourage public and private investment in the technologies that are likely to improve human health. This symposium will also be an opportunity for the presentation of the preliminary findings of the European market access study conducted at Charité under the sponsorship of the European Personalized Medicine Association, EPEMED.

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CENTRE DE RECHERCHE PUBLIC

EPEMED
The European Personalised Medicine Association

UNIVERSITY OF TWENTE.

FRED HUTCHINSON CANCER RESEARCH CENTER
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LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Directorate-General for Health & Consumers

THEMATIC SESSIONS (Monday 28 October 2013)

SESSION I - Welcome and Introductions (09:00-09:45)	
Jean-Claude Schmit, CEO, CRP- Santé	Welcome
Mars Di Bartolomeo, Minister of Health	Welcome
Maarten IJzerman, University of Twente	Luxembourg Institute for Translational Health Economics

SESSION II - Research & Development (09:45-11:15)	
This session will examine how economic methods can be used to inform R&D investment decisions for personalized medicine concepts very early in the developmental pipeline, with the goal of creating a quantitative framework for early investment decisions.	
Panel	**Pierre-Philippe Sagnier,** Moderator, Nestlé **Catherine Larue,** Integrated BioBank of Luxembourg **Ansgar Hebborn,** Head, Global Market Access Policy, Roche Pharma
Scott Ramsey, Fred Hutchinson Cancer Research Center	To Invest or Not to Invest: a Multi-Stakeholder Driven Approach to Early Cycle Economic Evaluation of Diagnostic Technologies
Leon Terstappen, University of Twente	Circulating Tumor Cells: A real time liquid biopsy for all cancer patients
Jennifer Harris, Norway Institute Public Health	Population-based and clinical-based biobanks for identifying research and public health needs: toward harmonization of biobanks.
Lotte Steuten, University of Twente	Early Assessment of Medical Technologies to Inform Product Development: Concepts and a Case Study

11:15-11:30 BREAK

SESSION III - Clinical & economic evidence (11:30-13:00)	
Technology and diagnostic developers face substantial uncertainty about the clinical and economic evidence that will be required to move a technology through phases of clinical development. This session will investigate evidence standards and suggest an evidentiary framework.	
Panel	**Scott Ramsey,** Moderator, Fred Hutchinson Cancer Research Center **Sabine Linn,** The Netherlands Cancer Institute **Robert Dann**, GE Healthcare
Uwe Siebert, Oncotyrol	Can Personalised Medicine and Public Health Improve Outcomes? Methodological Approaches and Evidence Requirements for Personalised Medicine, Diagnostics and Screening
Patrice Denèfle, IPSEN	Applying Translational Medicine in Health Industry: A Practical Example at IPSEN
Brett Hauber, RTI	Patient preference, heterogeneity and the value of advanced genomic information: whose values count?
Andrea Manca, University of York	Health Economic Evaluation and Personalised Care: Where To?

13:00-14:30 LUNCH

SESSION IV - Market authorization (14:30-16:00)	
Ongoing developments in personalized medicine place a challenge on market authorization and approval. How can we ensure drugs are used for targeted populations? And how should we deal with heterogeneity in clinical response and preferences of stakeholders?	
Panel	**Uwe Siebert,** Moderator, Oncotyrol **Wim Goettsch,** CVZ **Uwe Vosgerau,** Gemeinsamer Bundesauschuss (pending) **Juliette Plun-Favreau**, Genomic Health
Mondher Toumi, Creativ-Ceutical	Policy perspective on market authorization and evidence development for personalized medicine
Angela Brand, Maastricht University	European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome-based Information and Technologies
Hans-Georg Eichler, European Medicines Agency	Regulatory Decision-Making in the Context of Personalized Medicine: Consequences for authorization and pharmacovigilance

16:00-17:30 CLOSING RECEPTION

THEMATIC SESSIONS (Tuesday 29 October 2013)

Reimbursement, Market access and EPEMED study

Opening & agenda	**Alain Huriez**, Chairman, EPEMED
SESSION V - Reimbursement & Market Access Overview (09:00-10:15)	
Reimbursement of personalized medicines is a key issue in bringing new innovations to healthcare. But do existing methods for determining added value also apply to personalized medicines. And how should we evaluate health economic value in diagnostics driven medicine? This session will introduce ISPOR guidelines and discuss market access strategies and current trends in value based pricing.	
Panel	**Alain Huriez**, Moderator, Chairman EPEMED **Jesus Rueda**, Eucomed, EDMA and MedTech Europe **Uwe Vosgerau,** Gemeinsamer Bundesauschuss **Nick Crabb**, NICE
Katherine Payne, University of Manchester	ISPOR good research practices for the economic evaluation of personalized medicines
Ansgar Hebborn, Roche Pharma	Demonstrating the value of personalized medicine - issues and challenges facing technology developer
Josh Carlson, University of Washington	Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers

10:15-10:30 BREAK

Session VI - EPEMED European Market Access Study Release (10:30-12:30)	
Navigating Market Access challenges in Europe in 2013 for Personalised Medicine : a pan European Study conducted by Charité, Universitätsmedizin, Berlin	
Panel	**Ralph Riley**, Janssen Diagnostics **Joe Ferrara**, President, Boston Healthcare **Konstantinos Lykopoulos**, Director, Market Access, GSK Vaccines
Presenters & Moderators:	**Stefan Willich/Markus Bücheler**, Charité - Universitätsmedizin Berlin Institute for Social Medicine, Epidemiology, and Health Economics

Session VII - Closing Remarks and Adjourn (12:30)