ISPOR 18th Annual European Congress

7-11 NOVEMBER 2015
MICO – MILANO CONGRESSI
MILAN, ITALY

Impacting Health Decision Making with Outcomes Research: Closing the Gap

PROGRAM AND SCHEDULE OF EVENTS

ISPOR Congress App: see page 16
Wifi Network: Ispor
Password: Milan2015

www.ispor.org
Regional Chapters and Networks in Europe

8,700+ Regional Chapter Members

3,700+ Regional Chapter Members in Europe!

- Belarus Chapter
- Bosnia-Herzegovina Chapter
- Bulgaria Chapter
- Croatia Chapter
- Cyprus Chapter
- Czech Chapter
- Greece Chapter
- Hungary Chapter
- Italy-Milan Chapter
- Italy-Rome Chapter
- Poland Chapter
- Portugal Chapter
- Republic of Macedonia Chapter
- Romania Chapter
- Russia Chapter
- Russia Far East Chapter
- Russia HTA Chapter
- Russia St. Petersburg Chapter
- Serbia Chapter
- Slovakia Chapter
- Slovenia Chapter
- Spain Chapter
- Turkish SCP Chapter
- Ukraine Chapter

> If you are interested in joining ISPOR Regional Chapters in Europe, please contact: regionalchapter@ispor.org.
> If you are interested in joining the ISPOR Central and Eastern Europe Network, please contact ceenet@ispor.org.

ISPOR Publications in Europe

Value in Health is the official journal of ISPOR. It provides a forum for researchers, health care decision makers, and policy makers to translate pharmacoeconomics and outcomes research into health care decisions.

Value in Health Regional Issues publishes research and health policy articles specific to the Asia, Latin America, and Central & Eastern Europe, Western Asia and Africa (CEEWA) regions.

News Across Central & Eastern Europe, the ISPOR Central & Eastern Europe (CEE) Network newsletter, serves as a platform for the exchange of knowledge in the CEE region on current health care systems and policies, outcomes research, and education impacting health care research and policy decision making in CEE.

ISPOR Therapeutic and Diagnostic Device Outcomes Research book is available in Bosnian, Polish, Serbian, and Spanish.

ISPOR Book of Terms is available in multiple European languages.

> Access these publications at www.ispor.org >> “Publications”
Dear Colleagues,

As we celebrate ISPOR’s past accomplishments during our 20th Anniversary year, we are looking to a very bright future with our new strategic plan, updating Vision 2020.

Beginning with a planning session last winter, the Society’s Board of Directors and other leaders have been involved in crafting new Vision and Mission Statements, along with updating the areas of strategic focus. The evolving plan focuses on ISPOR’s ongoing commitment to strengthen the integrity, advancement, and understanding of health economics and outcomes research globally.

I am proud to share with you the Mission and Vision Statements approved by the ISPOR Board of Directors. The new ISPOR Mission Statement is:

- To promote health economics and outcomes research excellence to improve decision making for health globally.

In updating our new Vision and Mission Statement we emphasize the work that we do as researchers, payers, decision and policy makers, academicians, clinicians, and patients.

The previous Mission Statement, “To increase the efficiency, effectiveness, and fairness of health care to improve health,” did not focus specifically on health economic and outcomes research. We also wanted to reinforce our position as a global organization.

Our new Vision Statement:

- ISPOR is the leading global scientific and educational organization for health economics and outcomes research and their use in decision making to improve health.

The previous Vision Statement, “ISPOR is recognized globally as the authority for outcomes research and its use in health care decisions towards improved health,” did not include the importance of ISPOR’s role as a leading educational organization.

Along with the Vision and Mission, the Board approved 5 Strategic Pillars that support our Vision and Mission.

**SCIENTIFIC AND RESEARCH EXCELLENCE**

ISPOR is committed to strengthening the integrity, advancement, and the understanding and use of health economics and outcomes research among researchers, health technology developers and assessors, regulators, health economists, health care policy makers, payers, providers, patients, populations, and society.

**MEMBER ENGAGEMENT**

Through its worldwide membership and stakeholder groups, ISPOR has access to the ideas, knowledge, skills, and experiences that enable achievement of its mission. ISPOR offers membership benefits that are valued and essential in members’ professional growth.

**EDUCATION AND TRAINING**

Knowledge and skill building are at the core of the ISPOR mission. ISPOR will lead efforts to strengthen and expand capabilities in health economics and outcomes research.

**COMMUNICATION AND COLLABORATION**

ISPOR will be a valued and reliable resource for translating knowledge into practice for decision makers and stakeholders who include members, providers, payers, patients, professional societies, foundations, health authorities, the media, and others.

**ORGANIZATIONAL VALUES**

ISPOR embraces a core set of values and standards that underlie all that we do.

Over the next months, the plan with accompanying goal statements will be shared with the membership.

A special thank you to CEO and Executive Director Nancy Berg and her staff for driving this planning process, that involved dozens of members in a condensed time frame.

I personally invite you to join us at the Member Meeting, “Updating ISPOR Vision 2020,” on Tuesday, November 10 at the 18th Annual European Congress in Milan, Italy where I will present the plan and engage members in discussing the future of our Society.

Daniel C. Malone, RPh, PhD
2015-2016 ISPOR President
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Dear Colleagues,

With great pleasure we would like to welcome you to Milan for the ISPOR 18th Annual European Congress. The theme of the conference, “Impacting Health Decision Making with Outcomes Research: Closing the Gap,” will be centered on the use of outcomes assessment in decision making: Are we ready to use the developments and scientific endeavor of three decades of outcomes research for strategic policy making and day-to-day health services and technologies financing decisions?

In the opening plenary session on Monday, “Strategy in Motion: The Current and Future Lifecycle Approach to Decision Making on Health Technologies,” payers, health technology assessment (HTA) and regulatory leaders, patient and industry representatives, and key decision makers will discuss several issues including the new medical device regulation in Europe, the work underway within the Adaptive Pathways to Patients initiative for drugs, and the European Commission’s HTA network plans.

On Tuesday, in our second plenary session, “Outcomes Research: Are We Ready to Put Theory into Practice?”, thought-provoking, forward-looking practicing clinicians, HTA body representatives, and public health leaders from both sides of the Atlantic will share their views and discuss the applicability of outcomes assessment in day-to-day practice as well as in strategic decision making.

In the third plenary session scheduled for Wednesday, “Recommendations from the ISPOR Multi-Criteria Decision Analysis Emerging Good Practice Task Force and Remaining Controversies,” the ISPOR MCDA Task Force will discuss approaches for conducting MCDA and emerging good practices. This session will be shaped mostly as a panel discussion with experienced, thought-leading, and outspoken panelists discussing areas of controversy and emerging good practice recommendations.

This Congress is an important forum for acquiring more knowledge and for networking. The scientific novelty is not only guaranteed by activities such as pre-Congress short courses, issue panels, workshops, forums, symposia, podium presentations, and poster presentations, but also by the Social Event. The ISPOR Social Event will take place on Tuesday night: Enjoy a true Milanese experience at the historic Hotel Principe di Savoia in the heart of Milan! Network with colleagues and indulge in the finest classic Italian cuisine!

Furthermore, we hope that you have time to do some sightseeing in Milan, a wonderful city that gladly welcomes guests from all over the world and provides the opportunity to learn about art, fashion, sport, food, and wine - for which Milan is widely famous!

Finally, we would like to thank all who contributed to the ISPOR 18th Annual European Congress, especially the Review Committee Co-Chairs and the ISPOR staff. They have all already put great effort into making this Congress a success. ISPOR aims to promote health economics and outcomes research excellence to improve decision making for health globally: we can all contribute to this.

We hope that you enjoy the ISPOR 18th Annual European Congress and your stay in Milan.

We look forward to seeing you in Milan!

Sincerely,

Francois Meyer, MD
18th Annual European Congress Co-Chair
PROGRAM COMMITTEE CO-CHAIRS:

Lorenzo G. Mantovani, DSc
Associate Professor of Public Health, Research Center on Public Health (CESP), University of Milano-Bicocca, Monza, Italy

François Meyer, MD
Advisor to the President, International Affairs, French National Authority for Health (HAS), Saint-Denis La Plaine, France

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Managing Director, Institute for Pharmacoeconomic Research, Vienna, Austria

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Research Fellow, National School of Public Health and President of the Hellenic Association of Pharmacoeconomics, Athens, Greece

Paolo Angelo Cortesi, PhD
Researcher, Research Centre on Public Health (CESP), University of Milano-Bicocca, Monza, Italy

Anthony J Hatswell, MSc
Principal Consultant (HTA Methodology), BresMed and Department of Statistical Science, University College London, Sheffield, UK

ISSUE PANEL REVIEW COMMITTEE CO-CHAIRS:

Máirín Ryan PhD, DrPH
Director of Health Technology Assessment & Deputy Chief Executive Officer, Health Information and Quality Authority, Dublin, Ireland

Simona de Portu, MSc
Reimbursement Manager, Diabetes, EMEA, Medtronic International Trading Sàrl, Tolochenaz, Switzerland

Oriol Solà Morales, MD, PhD, MSc
Partner, Health Innovation Technology Transfer (HiTT) and Assistant Professor, Health Economics, International University of Catalonia (UIC), Barcelona, Spain

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Professor, Department of Pharmacy, University of Groningen, Groningen, The Netherlands

Bertalan Németh, MSc
Senior Health Economist, Syreon Research Institute, Budapest, Hungary

Tara Symonds, PhD
COA Strategy Lead & Partner, Clinical Outcomes Solutions Ltd., Folkestone, Kent, UK
**CONGRESS PROGRAM AT-A-GLANCE**

**SUNDAY, 8 NOVEMBER**

8:00-17:00  ALL DAY SHORT COURSES (Registration Required)

Bayesian Analysis – Overview and Applications  Brown 1 (L2)

8:00-12:00  MORNING SHORT COURSES (Registration Required)

New! Introduction to the Economic Analysis of Diagnostics Brown 2 (L2)

New! Discrete Event Simulation for Economic Analyses – Concepts Amber 1 (L2)

Use of Instrumental Variables in Observational Studies of Treatment Effects Amber 2 (L2)

Transferability of Cost-Effectiveness Data between Countries Brown 3 (L2)

Conjoint Analysis – Theory & Methods Space 3 (L0)

Budget Impact Analysis: A 6-Step Approach Space 2 (L0)

Risk-Sharing / Performance-Based Arrangements for Drugs and Other Medical Products Space 1 (L0)

12:00-13:00  LUNCH (Attendees on their own)

13:00-17:00  ALL DAY SHORT COURSES (Registration Required)

Budget Impact Analysis II: Applications & Design Issues Space 2 (L0)

Discrete Event Simulation for Economic Analyses – Applications Amber 2 (L2)

New! Mixed Methods Approaches for Patient-Centered Outcomes Research: Group Concept Mapping Amber 1 (L2)

Network Meta-Analysis in Relative Effectiveness Research Amber 3-4 (L2)

Patient Registries Brown 2 (L2)

New! Risk-Sharing / Performance-Based Arrangements in Central & Eastern Europe: Implementation of Managed Entry Agreements Space 3 (L0)

Reimbursement Systems for Pharmaceuticals / Biologics in Europe Space 1 (L0)

New! Using Multi-Criteria Decision Analysis in Health Care Decision Making: Approaches & Applications Brown 3 (L2)

17:30-18:30  EDUCATIONAL SYMPOSIUM Brown 3 (L2)

Big Data, Data Quality or Deep Data? Innovative Designs for Real-World Evidence Generation 18:45-19:45

EDUCATIONAL SYMPOSIUM Brown 3 (L2)

Innovative Pricing & the Relationship to Value: Strategic Market Access Planning & Execution 17:30-18:30

EDUCATIONAL SYMPOSIUM Space 1 (L0)

What Role Do Randomised Clinical Trials Have in Establishing the Value for Health Technologies? 8:45-14:15

RESEARCH POSTERS I South Hall (L0)

8:45-10:45  WELCOME & FIRST PLenary SESSION Gold (L2)

Strategy in Motion: The Current and Future Lifestyle Approach to Decision Making on Health Technologies 10:45-11:15

BREAK, EXHIBITS & RESEARCH POSTERS I South Hall (L0)

11:15-12:15  ISSUE PANELS - I


IP2: Possible Increased Synergy between Health Technology Assessment (HTA) and Regulatory Agencies: Opportunity or Challenge for Medical Devices? Brown 1-2 (L2)

12:15-14:15  LUNCH Gold View Lounge (L2)

19:45-21:00  ISPOR MEDICAL DEVICES SPECIAL INTEREST GROUP MEETING Open to all Attendees Brown 3 (L2)

IP3: Speed or Less Uncertainty? Trade-Offs in Adaptive Pathway Implementation and Potential Pricing and Reimbursement Responses Brown 3 (L2)

IP4: Management of Specialty Drugs in the United States and Europe: Are We Balancing Innovation and Affordability? Space 2 (L0)

IP5: Blog It, Tweet It, Like It, or Bin It? The Role of Social Media Data in Patient-Reported Outcomes Research Space 1 (L0)

12:15-14:15  POSTER AUTHOR DISCUSSION HOUR I South Hall (L0)

15:45-15:55  RESEARCH PODIUMS - I

Studies on Health Technology Assessment Agencies Gold (L2)

New! Budget Impact Analysis of Managed Entry Agreements for New Drugs Brown 1-2 (L2)

F1: Rare Disease Clinical Trials: Emerging Good Practices for Clinical Outcomes Assessment Outcomes (PROs, ClinROs & ObsROs) Measurement Gold (L2)

F2: Mapping to Estimate Utility Values for Cost per QALY Economic Analysis - Good Research Practices Brown 3 (L2)


F4: Health Technologies Pricing and Decision Making in the Central South Europe: What, Where, and How? Space 1 (L0)

F5: Parallel Trade: Can We Curb the Impact on Central & Eastern European (CEE) Countries? Space 1 (L0)

F6: Assessing Medication Adherence: Patient-Reported, Clinical, Pharmacoepidemiologic, and Economic Approaches Space 3 (L0)

F7: Defining and Valuing Innovation in Oncology Gold (L2)

F8: The PubMed & the P-Sub: A Potential Framework Developed to Assess the Need for and Design of Managed Entry Agreements for New Drugs Brown 1-2 (L2)

W1: Adjusting for Time-Dependent Confounding and Crossover Bias in Observational Studies and Clinical Trials: Purpose, Methods, and Acceptance in HTA Brown 3 (L2)

W2: Making Sense of Novel Approaches for Indirect Comparison: Similarities and Differences of Simulation and Matching Based Approaches Space 1 (L0)

W4: Guidance for Evidence Synthesis of Survival Outcomes for Cost-Effectiveness Modeling Space 2 (L0)

W5: Challenges and Opportunities in Heart Failure: Unmet Clinical Needs, Economic Burden, and Impact on Society Space 3 (L0)

10:45-12:15  RESEARCH PODIUMS - II

Cost-Effectiveness Studies Gold (L2)

Cardiovascular Disease Research Studies Space 2 (L0)

Health Technology Assessment Studies Brown 3 (L2)

Patient-Reported Outcomes Studies Space 3 (L0)

Research on Methods Studies – I Brown 1-2 (L2)

17:00-18:00  WORKSHOPS - I

W1: Identification, Valuation, and Translation of Policy Options Gold (L2)

W2: The Efficacy and the Efficacy of the Evidence: Methods and Applications in Pharmacokinetics and Pharmacodynamics Gold (L2)

W3: Mapping to Estimate Utility Values for Cost per QALY Economic Analysis - Good Research Practices Brown 3 (L2)


W5: Identifying, Valuing, and Synthesizing Evidence: Linking Economic Evaluations to Policy Decision-Making Gold (L2)

W6: Assessing Medication Adherence: Patient-Reported, Clinical, Pharmacoepidemiologic, and Economic Approaches Space 3 (L0)

W7: Risk-Sharing in New Drugs Brown 3 (L2)

W8: The Role of Economic Evaluation in the Development of New Technologies Brown 1-2 (L2)

W9: Challenges and Opportunities in Heart Failure: Unmet Clinical Needs, Economic Burden, and Impact on Society Space 3 (L0)

W10: Responsible Scientific Translation of Economic Evaluation in Decision Making Brown 1-2 (L2)

W11: Economic Evaluation in the Context of Public Health Brown 1-2 (L2)


W13: Mapping to Estimate Utility Values for Cost per QALY Economic Analysis - Good Research Practices Brown 3 (L2)

W14: Evaluating the Cost-Effectiveness of Innovation: A Framework for Assessing the Value of New Technologies Gold (L2)


W16: Assessing Medication Adherence: Patient-Reported, Clinical, Pharmacoepidemiologic, and Economic Approaches Space 3 (L0)

18:00-19:45  EXHIBITORS’ OPEN HOUSE RECEPTION & RESEARCH POSTERS I South Hall (L0)

18:15-19:15  ISPOR FORUMS - I

F1: Rare Disease Clinical Trials: Emerging Good Practices for Clinical Outcomes Assessment Outcomes (PROs, ClinROs & ObsROs) Measurement Gold (L2)

F2: Mapping to Estimate Utility Values for Cost per QALY Economic Analysis - Good Research Practices Brown 3 (L2)


F4: Health Technologies Pricing and Decision Making in the Central South Europe: What, Where, and How? Space 1 (L0)

F5: Parallel Trade: Can We Curb the Impact on Central & Eastern European (CEE) Countries? Space 1 (L0)

F6: Budget Restrictions Following the Economic Crisis: Threats or Opportunities for the Development of Economic Evaluation in the Southern European Region Space 3 (L0)

F7: Defining and Valuing Innovation in Oncology Gold (L2)

F8: The PubMed & the P-Sub: A Potential Framework Developed to Assess the Need for and Design of Managed Entry Agreements for New Drugs Brown 1-2 (L2)

W1: Adjusting for Time-Dependent Confounding and Crossover Bias in Observational Studies and Clinical Trials: Purpose, Methods, and Acceptance in HTA Brown 3 (L2)

W2: Making Sense of Novel Approaches for Indirect Comparison: Similarities and Differences of Simulation and Matching Based Approaches Space 1 (L0)

W3: Guidance for Evidence Synthesis of Survival Outcomes for Cost-Effectiveness Modeling Space 2 (L0)


W5: Identifying, Valuing, and Synthesizing Evidence: Linking Economic Evaluations to Policy Decision-Making Gold (L2)

W6: Assessing Medication Adherence: Patient-Reported, Clinical, Pharmacoepidemiologic, and Economic Approaches Space 3 (L0)
ISPOR INVITATIONAL GROUP MEETINGS

The following is a listing of the ISPOR invitation only group meetings being held during the ISPOR 18th Annual European Congress. ISPOR members worldwide are actively participating in ISPOR working groups to advance global health outcomes research and the use of this research in health care decisions. These ISPOR groups provide an opportunity for members to contribute to translating outcomes research to health care decisions.

*Please note that these meetings are by prior invitation only.*

### SATURDAY, 7 NOVEMBER

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<td>ISPOR Publications Management Advisory Board and Journal Editor-in-Chiefs Joint Business Meeting</td>
<td>Hotel Melia, Ambra Room</td>
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<td>11:30-17:00</td>
<td>ISPOR Board of Directors</td>
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<td>ISPOR HTA Roundtable</td>
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<td>12:30-14:00</td>
<td>ISPOR Economic Evaluation of Vaccines Designed to Prevent Infectious Disease Task Force</td>
<td>Amber 6 (L2)</td>
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<td>16:00-17:00</td>
<td>ISPOR Turkish SCP Chapter</td>
<td>Amber 6 (L2)</td>
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<td>17:15-18:45</td>
<td>ISPOR Conjoint Analysis Statistical Analysis Task Force</td>
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<td>17:30-18:30</td>
<td>ISPOR <em>Value in Health Regional Issues</em> Editorial Board &amp; Editorial Advisory Board (CEEWAA)</td>
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### MONDAY, 9 NOVEMBER

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<td>ISPOR Asia Consortium Business Meeting</td>
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<td>ISPOR <em>Value &amp; Outcomes Spotlight</em> Editorial Board</td>
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<td>7:30-8:30</td>
<td>ISPOR Nutrition Economics Special Interest Group</td>
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<td>11:00-13:00</td>
<td>ISPOR Spain Chapter</td>
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<td>12:00-13:00</td>
<td>ISPOR Institutional Council</td>
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<td>12:00-14:00</td>
<td>ISPOR <em>Value in Health</em> Editorial Board</td>
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<td>12:15-13:45</td>
<td>ISPOR CEE Network Executive Committee</td>
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<td>ISPOR Patient Representatives Roundtable</td>
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<td>ISPOR Educational Forum: Resilient Drug Policy in Emerging Markets, How MCDA Will Help the Emerging Policy Development</td>
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<td>ISPOR Value Assessment of Medical Devices Working Group</td>
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<td>ISPOR Regional Network Chairs</td>
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<td>14:30-16:30</td>
<td>ISPOR Measurement of HSUV for Economic Models Task Force</td>
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<td>15:00-16:00</td>
<td>ISPOR International Digest of Databases Special Interest Group</td>
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<td>ISPOR Hungary Chapter</td>
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<td>16:30-17:30</td>
<td>ISPOR Russia HTA Chapter</td>
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<td>16:30-17:30</td>
<td>ISPOR Israel Chapter</td>
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<td>16:30-18:00</td>
<td>ISPOR Optimization Methods in Health Systems and Outcomes Research Task Force</td>
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<td>19:45-20:45</td>
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<td>Amber 1-2 (L2)</td>
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### TUESDAY, 10 NOVEMBER

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<td>7:30-8:30</td>
<td>ISPOR Arabic &amp; ISPOR Africa Networks</td>
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<td>12:00-13:00</td>
<td>ISPOR Student Network &amp; Faculty Advisor Luncheon</td>
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<td>ISPOR CEE Network Working Committees</td>
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<td>ISPOR Multi Criteria Decision Analysis Task Force</td>
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<td>12:00-13:30</td>
<td>ISPOR Medication Adherence and Persistence Special Interest Group</td>
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<td>12:15-13:30</td>
<td>ISPOR Patient Representative Roundtable</td>
<td>Amber 6 (L2)</td>
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<td>13:45-15:15</td>
<td>ISPOR Measurement of COA in Rare Disease Clinical Trials Task Force</td>
<td>Amber 7 (L2)</td>
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<td>14:00-16:00</td>
<td>ISPOR Mapping to Estimate HSUV Non-Preference Based Economic Analysis Task Force</td>
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<tr>
<td>16:30-17:30</td>
<td>ISPOR Ukraine Chapter</td>
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### WEDNESDAY, 11 NOVEMBER

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<td>ISPOR Slovakia Chapter</td>
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<td>12:45-13:45</td>
<td>ISPOR Italy-Rome Chapter</td>
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<tr>
<td>13:00-15:30</td>
<td>ISPOR HTA Training Program Material Overview for Prospective Faculty</td>
<td>Amber 7 (L2)</td>
</tr>
<tr>
<td>15:45-18:00</td>
<td>ISPOR HTA Council</td>
<td>Amber 7 (L2)</td>
</tr>
</tbody>
</table>

**PLEASE NOTE:** INVITEES WILL RECEIVE AN EMAIL REMINDER AND NOTIFICATION OF ANY CHANGES TO THIS ISPOR GROUP MEETING SCHEDULE
SOUTH WING (Gates 2 & 17)

LEVEL MEZZANINE

LEVEL +2 (L2)

LEVEL +1 (L1)

LEVEL 0 (L0)

South Hall
Exhibit & Poster Hall
Monday-Wednesday

Networking Lounges

Space 1-4

Networking Lounge

Mobile App Help Desk

LEVEL +3 (L3)

Panorama Lounge
(Access via elevators in Gold View Lounge)
ANNUAL CONGRESS OBJECTIVES
Participants will be able to:
• Learn new pharmacoeconomic methodologies and outcomes research techniques;
• Improve the quality of their decision making by better utilization of pharmacoeconomic studies; and
• Learn the latest about measuring quality of life and selecting appropriate survey instruments.

REGISTRATION MATERIALS
The following materials will be printed with your name badge:
• Short Course ticket for each Short Course for which you registered (you MUST bring your Short Course ticket to the room to collect your materials and be admitted);
• One complimentary drink ticket to the Exhibitors’ Open House Reception: Monday, 9 November: 18:00-19:45;
• One complimentary drink ticket to the Exhibitors’ Wine & Cheese Reception: Tuesday, 10 November: 17:30-19:15;
• Social Event ticket (if pre-registered); and
• Continuing Education ticket (if pre-registered).

PLEASE NOTE: Registration bags, lanyards, Program & Schedule of Events, and Value in Health Volume 18, Issue 7 are available for pick-up near ISPOR registration.

CONGRESS REGISTRATION/SESSIONS
Separate registration is required for all Short Courses (Saturday, 7 November and Sunday, 8 November) and for the Social Event (Tuesday, 10 November). Please see ISPOR Registration for details. A schedule of ISPOR Group meetings, which are by invitation only, is provided on page 9. Congress registration is inclusive of symposia on Saturday, 7 November and Sunday, 8 November and for all sessions Monday-Wednesday, no pre-registration is required.

ISPOR REGISTRATION HELP DESK HOURS
ISPOR Registration is located in the main entrance of the South Wing Building near the Gate 2 Entrance (Level 1).
• Saturday, 7 November: 8:00-18:00
• Sunday, 8 November: 7:00-18:00
• Monday, 9 November: 7:00-18:00
• Tuesday, 10 November: 7:00-18:00
• Wednesday, 11 November: 7:00-16:00

EXHIBIT HALL HOURS
Exhibits are located in South Hall (Level 0).
• Monday, 9 November: 8:30-19:45
• Tuesday, 10 November: 8:30-19:15
• Wednesday, 11 November: 8:30-15:00

ISPOR MEETING APP
Access the mobile app on your smartphone or use the https://myispormilan.zerista.com/ website on your computer or tablet. Both options allow users to:
• Update your “electronic business card” (personal profile);
• Create a personalized Congress schedule;
• Search the Congress program by scientific topic, keyword, or speaker;
• Connect with other attendees by sending messages (while keeping your email address private); and
• Find exhibitors and sponsors to connect with by reviewing their profiles and information

Search for “ISPOR 2015 Meetings” in the App Store or on Google Play! The ISPOR 2015 Meetings app is compatible with Apple and Android devices and is available for download in the App Store and Google Play.
An “App Squad Help Desk” is located on the Balcony (Level 1) near ISPOR Registration with the following opening hours:
• Sunday, 8 November 14:00-18:00
• Monday, 9 November 8:00-18:00
• Tuesday, 10 November 8:00-18:00
See page 16 for more information.

INTERNET & WI-FI ACCESS
Internet stations are provided in South Hall (Level 0) (Exhibit and Poster Hall).
For the convenience of Congress attendees, Wi-Fi is available using the “Ispor” network with code “Milan2015” (case sensitive).
Wi-Fi is only intended for checking of email, use of the Congress app, etc., not downloading of files. Connection speeds will vary depending on the volume of users.
Wi-Fi and internet stations are sponsored by Pharmerit International.

RESEARCH PODIUM & POSTER ABSTRACTS
Abstracts for all podium and poster research presentations given at the ISPOR 18th Annual European Congress are published in Value in Health Volume 18, Issue 7. The page numbers to the left of the research podium and poster listings refer to the research abstract page number in this issue. Value in Health Volume 18, Issue 7 is available to ISPOR members and 18th Annual European Congress registrants online at: http://www.ispor.org/valueinhealth_index.asp. You can pick up a hard copy of this issue of Value in Health near ISPOR Registration.

FINANCIAL DISCLOSURE INFORMATION
Research podium and poster presentation financial disclosure information is available online at: http://www.ispor.org/valueinhealth_index.asp and in Value in Health Volume 18, Issue 7. Faculty and staff involved in the planning or presentation of this Congress are required to disclose all real or apparent commercial financial affiliations related to Congress content. This information is available on request at the ISPOR Registration desk.

PRESENTATION SLIDES/POSTERS
Congress plenary session, issue panel, workshop, ISPOR forum, and symposia slides will be available via the Congress App and at the 18th Annual European Congress Released Presentations page at www.ispor.org during/after the Congress, subject to speaker approval.
Podium and poster presentation abstracts and released slides or poster PDFs are available at the ISPOR Scientific Presentations Database (a searchable database of nearly 34,500 research papers presented at ISPOR meetings) at http://www.ispor.org/research_study_digest/index.asp or scan this QR code.

HANDBOUTS
• Plenary Sessions: Handouts for the plenary sessions are available in the session room at the time of the presentations.
• Research Presentations, Workshops, and Issue Panels: Handouts for research (podiums and posters), workshops, and issue panels are the sole responsibility of the presenting author(s).
• ISPOR Forums: Handouts for ISPOR Forums are available in the session room at the time of the presentations.
ABSTRACT SUBMISSION HISTORICAL INFORMATION

During the ISPOR 18th Annual European Congress, 2376 posters, 48 research podiums, 33 workshops, and 20 issue panels will be presented.

<table>
<thead>
<tr>
<th>Year</th>
<th>Research</th>
<th>Workshop</th>
<th>Issue</th>
<th>Panel</th>
<th>Case</th>
<th>Studies</th>
<th>Total</th>
<th>Accepted (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>1570</td>
<td>85</td>
<td>31</td>
<td>10</td>
<td>1696</td>
<td>9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2012</td>
<td>1705</td>
<td>90</td>
<td>47</td>
<td>9</td>
<td>1851</td>
<td>11.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2013</td>
<td>1888</td>
<td>103</td>
<td>55</td>
<td>-20</td>
<td>2046</td>
<td>10.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td>2168</td>
<td>117</td>
<td>60</td>
<td>-2345</td>
<td>2345</td>
<td>9.3%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>2592</td>
<td>97</td>
<td>78</td>
<td>-2767</td>
<td>2767</td>
<td>10.5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SPEAKER INFORMATION

Upload the final version of your slide presentation in the Speaker Ready Room on the same day of your session! All speakers are encouraged to use the Speaker Ready Room to preview their slide presentation and/or upload an updated version. Presentations submitted to ISPOR Speaker’s Corner by the specified advance deadline and all presentations uploaded/updated in the Speaker Ready Room 30 minutes prior to the session will be pre-loaded to the computer in the session room. All speakers are requested to arrive at their presentation room 15 minutes prior to the session start time. ISPOR staff will be available in the session room to assist the presenter.

A speaker ready room is provided in Suite 1 (Level 2) with the following opening hours:
- Sunday, 8 November: 12:00-18:00
- Monday, 9 November: 8:00-18:00
- Tuesday, 10 November: 8:00-18:00
- Wednesday, 11 November: 8:00-15:00

A business center/copy service is located in the MiCo Staff Office, located on the Balcony (Level 1).

Email: ispor2015meetings@fieramilanocongressi.it

For several copies and larger print jobs, attendees are advised to make arrangements via email.

ISPOR RESEARCH PRESENTATION AWARDs

Awards are given for the best research presentations for podiums and posters in the categories of GENERAL, NEW INVESTIGATOR, and STUDENT (up to 3 in each category).

All research podium presentations are considered for an award. The top 100 research poster presentations, based on abstract review score, are considered for a poster presentation award. These are identified with a rosette and will be judged during the Congress.

ISPOR 18th Annual European Congress Research Presentation Awards will be presented immediately after the 3rd Plenary Session on Wednesday, 11 November at 12:30.

CONTINUING MEDICAL & CONTINUING PHARMACEUTICAL EDUCATION ACCREDITATION

NOTE: Continuing Education Accreditation is offered in conjunction with the ISPOR Short Course Program only. Other Congress sessions and presentations are not accredited.

For pharmacists (CPE): Attendees may earn up to 4 CPE credits per each four hours of accredited half-day short course attendance, and up to 7.5 CPE credits per each eight hours of accredited full day short course attendance. Purdue University College of Pharmacy is accredited by the Accreditation Council on Pharmacy Education as a provider of continuing pharmacy education. This is a knowledge-based, continuing education activity of Purdue University, an equal access/equal opportunity institution. Complete UAN, CPE and disclosure information is listed within the Continuing Education Attendance and Evaluation Booklet. To receive credit for these continuing education activities, pharmacists must attend the entire program and complete all registration and evaluations at its conclusion.

For physicians (CME): This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education through the joint sponsorship of Purdue University College of Pharmacy and ISPOR. Purdue University College of Pharmacy, an equal access/equal opportunity institution, is accredited by the ACCME to provide continuing medical education for physicians. Purdue University College of Pharmacy designates this live activity for a maximum of up to 4 AMA PRA Category 1 Credit(s)™ per four hours of accredited half-day short course attendance, and up to 7.5 AMA PRA Category 1 Credit(s)™ per eight hours of accredited full day short course attendance, toward the AMA Physician’s Recognition Award. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

INSTRUCTIONS:

If you pre-registered: A Continuing Education materials ticket will be printed with your name badge. Registrants can redeem this ticket for the ISPOR 18th Annual European Congress Continuing Education Attendance and Evaluation Booklet at the onsite registration help desk.

To register on-site: Please visit the registration help desk. The fee for this service is €85 (USD$100).

To receive continuing education credits: Complete the ISPOR 18th Annual European Congress Continuing Education Attendance and Evaluation Booklet and return the entire Evaluation Booklet to the ISPOR registration help desk at the end of the Congress OR send to the ISPOR office within two weeks of the close of the Congress.

For CME: Certificates of participation will be sent 6-10 weeks after receipt of Evaluation Booklet to those who register and complete the program evaluation.

Accreditation for the ISPOR 18th Annual European Congress Short Course Program is co-sponsored by the International Society for Pharmacoeconomics and Outcomes Research and the Purdue University College of Pharmacy, Continuing Education Division.
### RESEARCH POSTER PRESENTATIONS

Poster presentations will be on view in **South Hall (Level 0)**.

The poster hall is organized in rows (A-P) and each poster board is numbered accordingly (e.g., A1, L10). Poster presentation titles and authors, as well as the numbered board location and abstract page reference in *Value in Health*, are available on the [myISPORMilan.zerista.com](https://myISPORMilan.zerista.com) web platform and ISPOR Milan mobile app. This information is also available as a PDF on the ISPOR website and as a handout at the Poster Help desk (please note quantities are limited).

Each poster presentation has been assigned a specific numbered board location, which is shown next to the presentation title. Please note this is different than the poster code (based on the abstract’s scientific topic), which was assigned to each poster presentation upon acceptance. Poster board numbering is shown on the floor plan on page 43 in the Program & Schedule of Events, as well as the website and mobile app. Row locations are also shown in the table below in **red**.

*Presenters are required to be with their posters during the Poster Author Discussion Hour.

**Posters that are not removed during the scheduled dismantle times will be discarded.**

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<table>
<thead>
<tr>
<th>POSTER PRESENTATION SESSIONS</th>
<th>POSTER LOCATION</th>
<th>POSTER DISPLAY HOURS</th>
<th>AUTHOR DISCUSSION HOURS</th>
<th>PRESENTER SET UP TIME</th>
<th>PRESENTER DISMANTLE TIME**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SESSION I: MONDAY, 9 NOVEMBER</strong></td>
<td>(See pages 42-43 for Information)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PMD: MEDICAL DEVICE/DIAGNOSTICS</td>
<td>ROWS A-F</td>
<td>8:45-14:15</td>
<td>13:15-14:15</td>
<td>8:30-8:45</td>
<td>14:15</td>
</tr>
<tr>
<td>PCV: CARDIOVASCULAR DISORDERS</td>
<td>ROWS F-L</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PMH: MENTAL HEALTH</td>
<td>ROWS L-M</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PSS: SENSORY SYSTEMS DISORDERS</td>
<td>ROWS M-P</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SESSION II: MONDAY, 9 NOVEMBER</strong></td>
<td>(See pages 42-43 for Information)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRS: RESPIRATORY-RELATED DISORDERS</td>
<td>ROWS L-O</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PUK: URINARY/KIDNEY DISORDERS</td>
<td>ROWS O-P</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>SESSION III: TUESDAY, 10 NOVEMBER</strong></td>
<td>(See pages 42-43 for Information)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHP: HEALTH CARE USE &amp; POLICY STUDIES</td>
<td>ROWS A-L</td>
<td>8:45-13:45</td>
<td>12:45-13:45</td>
<td>8:30-8:45</td>
<td>13:45</td>
</tr>
<tr>
<td>PIN: INFECTION</td>
<td>ROWS L-P</td>
<td></td>
<td></td>
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<tr>
<td><strong>SESSION IV: TUESDAY, 10 NOVEMBER</strong></td>
<td>(See pages 42-43 for Information)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>PGI: GASTROINTESTINAL DISORDERS</td>
<td>ROWS E-H</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PMS: MUSCULAR-SKELETAL DISORDERS</td>
<td>ROWS H-L</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>PSY: SYSTEMIC DISORDERS/CONDITIONS</td>
<td>ROWS L-P</td>
<td></td>
<td></td>
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<tr>
<td><strong>SESSION V: WEDNESDAY, 11 NOVEMBER</strong></td>
<td>(See pages 42-43 for Information)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PRM: RESEARCH ON METHODS</td>
<td>ROWS A-J</td>
<td>8:45-13:45</td>
<td>12:45-13:45</td>
<td>8:30-8:45</td>
<td>13:45</td>
</tr>
<tr>
<td>PIH: INDIVIDUAL’S HEALTH</td>
<td>ROWS J-M</td>
<td></td>
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<tr>
<td>PND: NEUROLOGICAL DISORDERS</td>
<td>ROWS M-P</td>
<td></td>
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</tbody>
</table>

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*Use the mobile app to search posters by topic, keyword, or author and add posters you would like to view to “My Posters.” See page 16 for more information.*
Enjoy a true Milanese experience at the historic Hotel Principe di Savoia, centrally located in the heart of Milan! Network with colleagues and indulge in the finest classic Italian cuisine.

Separate registration required: €90 per person. Price includes buffet dinner, beer and wine, and round trip transportation from the MiCo – Milano Congressi, returning to Congress hotels.

Registration subject to availability; see the ISPOR Registration desk for details.

For Social Event Registrants:

- If you have pre-registered for the Social Event, your ticket will print out with your name badge. You will need this ticket for entry to the bus/event.
- Buses will depart from the MiCo – Milano Congressi between 19:30 and 20:30 for the 15 minute journey to the Hotel Principe di Savoia.
- Return buses will start at 21:00, last bus at 23:30. Buses will depart every 30 minutes and different routes will serve various Congress hotels. Please see drivers for additional information.

ISPOR SOCIAL MEDIA

Communicating by way of social media is encouraged if it falls within the embargo and communications guidelines. Be part of the live discussion!

- Tweet to @ISPORorg during the Congress using #ISPORMilan
- Access expert insights and share your views on Congress sessions at the ISPOR LinkedIn Discussion Group: http://bit.ly/ISPOR-IN
- Network with your peers on the ISPOR Facebook page: http://bit.ly/ISPOR-FB

RECORDING & PRESS INFORMATION

ISPOR supports the promotion of research presented at ISPOR meetings, while safeguarding sensitive information, data, and research findings that are not yet available to the public. Due to the sensitive nature of data and particularly preliminary, unpublished research findings, all filming and recording of scientific sessions and the poster hall is prohibited during the Congress, without the express consent of ISPOR.

Portions of the ISPOR 18th Annual European Congress may be recorded by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). By participating in the discussions, Congress registrants agree that ISPOR may electronically copy, videotape, or audiotape their attendance at and involvement in any program. Registration and attendance at the ISPOR 18th Annual European Congress constitutes an agreement by the registrant to ISPOR’s use and distribution (both now and in the future) of their image or voice in photographs, videotapes, electronic reproductions, and audiotapes of such events and activities. ISPOR will strictly enforce its rights as the exclusive licensee of all publication and reproduction rights to each presentation, and no presentation, in whole or in part, may be reproduced without approval from ISPOR.

Congress attendees must gain approval from a speaker or poster presenter prior to quoting or publishing that individual’s scientific results. Members of the press must identify themselves as such before questioning speakers and Congress attendees if using the information in a professional capacity.

More detailed information on ISPOR’s Press Pass, Legal, and Embargo Policies are available on ISPOR’s News & Press page at the ISPOR website (www.ispor.org).

For further questions on these policies, please contact: Betsy Lane (blane@ispor.org), Director and Chief Marketing & Communications Officer.

CONGRESS PROGRAM DISCLAIMER

Please be advised that while the Congress program is designed to provide accurate information regarding the subject matter covered, the views, opinions, and recommendations expressed are those of the authors and speakers, not the International Society for Pharmacoeconomics and Outcomes Research (ISPOR), and thus ISPOR does not guarantee the accuracy of the information disseminated. If professional advice is desired, please consult a competent professional.

ANTITRUST COMPLIANCE

It is the undeviating policy of ISPOR to comply strictly with the letter and spirit of all Federal, State, and applicable international trade regulations and antitrust laws. Any activities of ISPOR or ISPOR-related actions of its officers, Executive Committee Members, or members that violate these regulations and laws are detrimental to the interests of ISPOR and are unequivocally contrary to ISPOR policy.

QUESTIONS & INFORMATION

Please ask ISPOR staff members for any additional information about the Congress or about ISPOR. ISPOR staff can be identified by their black shirts with ISPOR logo.
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ISPOR 2015 Meetings

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Need help? Select “Need help logging in?” on the login screen.

APP FEATURES:

TOUCH THE MENU ICON ☰ TO ACCESS THE FOLLOWING:
- Program
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- Posters
  Search posters by topic, disease, keyword, or author.
- Released Presentations
  Access presentation slides from congress sessions.
- Key Information
  Key meeting information.
- Invitational Meetings
  A schedule of ISPOR Group Meetings that are by invitation only.
- Attendees
  Network with other attendees.
- Chatter
  See what others are saying about the congress & join the discussion.
- Maps
  Access maps for congress rooms, posters, and exhibits.

Have questions or need help?
Visit the App Squad Help Desk on the Balcony (Level 1)

No smart phone or tablet? Use your laptop: myispormilan.zerista.com
Internet stations are also provided in South Hall (Level 0)
ISPOR 18th Annual European Congress
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SHORT COURSE PROGRAM

www.ispor.org #ISPORMilan
Economic evaluations are important within the entire life cycle of health innovations. Uncertainty analyses, discounting, perspective of the analysis, and to how health are discussed. Special attention is moreover given to specific issues such as alternatives. Both modelling techniques and prospective health economic evaluations are discussed. Special attention is moreover given to specific issues such as uncertainty analyses, discounting, perspective of the analysis, and to how health economic evaluations are important within the entire life cycle of health innovations.

**ISPOR SHORT COURSES**

**SATURDAY, 7 NOVEMBER**

**ALL DAY COURSE 9:00-18:00**

**INTRODUCTION TO HEALTH ECONOMIC / PHARMACOECONOMIC EVALUATIONS Space 1 (L0)**

**TRACK Economic Methods**

**LEVEL** Introductory. This course is suitable for those with little or no experience with pharmacoeconomics.

**FACULTY** Lieven Annemans, PhD Econ, MSc Health, Senior Full Professor of Health Economics, ICHER (Interuniversity Center for Health Economics Research), Ghent University - Brussels University, Ghent, Belgium

**COURSE DESCRIPTION** This course is designed to teach health care professionals, industry executives and new researchers how to incorporate health economics/pharmacoeconomics into the development of innovations in health care. Participants will review the basic principles and concepts of health economic evaluations, and discuss how to collect and calculate data on costs and effects of different alternatives. Both modelling techniques and prospective health economic evaluations are discussed. Special attention is moreover given to specific issues such as uncertainty analyses, discounting, perspective of the analysis, and to how health economic evaluations are important within the entire life cycle of health innovations.

**INTRODUCTION TO THE DESIGN & ANALYSIS OF OBSERVATIONAL STUDIES OF TREATMENT EFFECTS USING RETROSPECTIVE DATA SOURCES Brown 2 (L2)**

**TRACK Observational Data Methods**

**LEVEL** Introductory.

**FACULTY** Bradley C. Martin, PharmD, RPh, PhD, Professor & Head, Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences College of Pharmacy, Little Rock, AR, USA; Linus Jönsson, PhD, MD, MSc, Vice President, Medical Outcomes Research, H. Lundbeck, Denmark

**COURSE DESCRIPTION** Retrospective studies require strong principles of epidemiologic study design and complex analytical methods to adjust for bias and confounding. This course will provide an overview of the structures of commonly encountered retrospective data sources with a focus on large administrative data, as well as highlight design and measurement issues investigators face when developing a protocol using retrospective observational data. Approaches to measure and control for patient mix, including patient comorbidity and the use of restriction and stratification, will be presented. Linear multivariable regression, logistic regression, and propensity scoring analytic techniques will be presented and include examples using SAS code that can later be used by participants. This course is an introductory course designed to prepare participants to take intermediate and advanced observational research courses.

**INTRODUCTION TO PATIENT-REPORTED OUTCOMES ASSESSMENT: INSTRUMENT DEVELOPMENT & EVALUATION Amber 2 (L2)**

**TRACK Patient-Reported Outcomes Methods**

**LEVEL** Introductory. This is an entry level course which assumes only a passing familiarity with patient-reported outcomes.

**FACULTY** Andrew Lloyd, DPhil, Director, Bladon Associates Ltd., Oxford, UK; Kellee Howard, MA, MSc, Director, Patient Reported Outcomes, ICON Commercialisation & Outcomes, San Francisco, CA, USA

**COURSE DESCRIPTION** Patient-reported outcomes (PROs) are widely used to evaluate the impact of health technologies, practice innovations, or changes in health policy from the patients’ perspective. This course is designed to familiarize people with the range and scope of what PROs are used for, how they are developed and evaluated, what they measure, and how PRO data can be used to support licensing and reimbursement applications. This includes generic and disease-specific measures of health-related quality of life (HRQL) as well as measures of patient preference, systems, functioning, utility, and treatment satisfaction. The faculty will describe the steps that researchers generally go through in order to develop and test a new PRO. This will include qualitative work, item generation and testing, and then validation. Finally, in the last hour, faculty will frame this in terms of what the FDA and EMA expect to see when PROs form an important part of a licensing submission. In addition, faculty will describe the approach of bodies such as NICE and how they review PRO data and use it to guide reimbursement decisions.
COURSE DESCRIPTION The growing number of prospective clinical/economic trials reflects both widespread interest in economic information for new technologies and the regulatory and reimbursement requirements of many countries that now consider evidence of economic value along with clinical efficacy. This course will present the design, conduct, and reporting of cost-effectiveness analyses alongside clinical trials based on, in part, Good Research Practices for Cost-Effectiveness Analysis alongside Clinical Trials: The ISPOR RCT-CEA Task Force Reports. Trial design, selecting data elements, database design and management, analysis, and reporting of results will all be presented. Trials designed to evaluate effectiveness (rather than efficacy), as well as clinical outcome measures, will also be discussed, including how to obtain health resource use and health state utilities directly (rather than efficacy), as well as clinical outcome measures, will also be discussed, including how to obtain health resource use and state utilities directly from study subjects and economic data collection fully integrated into the study. Analyses guided by an analysis plan and hypotheses, an incremental analysis using an intention to treat approach, characterization of uncertainty, and standards for reporting results will be presented.

ELEMENTS OF PHARMACEUTICAL / BIOTECH PRICING Brown 3 (L2)

TRACK Use of Pharmacoeconomic / Economic / Outcomes Research Information Methods

LEVEL Introductory. This course is designed for those with limited experience in the area of pharmaceutical pricing and will cover topics within a global context.

FACULTY Jack M. Mycka, Global President and CEO, MME LLC, Montclair, NJ, USA; Renato Dellamano, PhD, President, MME Europe & ValueVector (Value Added Business Strategies), Milan, Italy

COURSE DESCRIPTION This course will give participants a basic understanding of the key terminology and issues involved in pharmaceutical pricing decisions. It will cover the tools to build and document product value including issues, information, and processes employed (including pricing research), the role of pharmacoeconomics, and the differences in payment systems that help to shape pricing decisions. These tools will be further explored through a series of interactive exercises.
course will also illustrate the need to consider various aspects when developing conceptual models (including the decision problem, service framework, disease pathway, causal pathway, and quantitative model design aspects) and will provide overview of useful graphical tools for illustrating these aspects.

USE OF PROPENSITY SCORES IN OBSERVATIONAL STUDIES OF TREATMENT EFFECTS

TRACK Observedatal Data Methods

LEVEL Intermediate. This course is designed for those with little experience with this methodology but some knowledge of observational databases.

PREREQUISITE Previous attendance at the ISPOR short course "Introduction to the Design & Analysis of Observational Studies of Treatment Effects Using Retrospective Data Sources", or equivalent knowledge, is recommended.

FACULTY John Seeger, PharmD, DrPH, Assistant Professor of Medicine, Division of Pharmacoeconomics and Pharmacoconomics, Harvard Medical School/Brigham and Women's Hospital, Boston, MA, USA; Jeremy Rassen, ScD, Chief Scientific Officer, Aetion, Inc., New York, NY, USA

COURSE DESCRIPTION In observational research, issues of bias and confounding relate to study design and analysis in the setting of non-random treatment assignment where compared subjects might differ substantially with respect to comorbidities. No control over the treatment assignment and the lack of balance in the covariates between the treatment and control groups can produce confounded estimates of treatment effect. Faculty will explain how propensity scores can be used to mitigate confounding through standard observational approaches (restriction, stratification, matching, regression, or weighting). The advantages and disadvantages of standard adjustment relative to propensity score-based methods will be discussed. Details of propensity score methodology (variable selection, use, and diagnostics) will also be discussed. The course will also elaborate briefly on risk adjustment models that collapse predictors of outcomes and their use relative to propensity scores.

INTRODUCTION TO PATIENT PREFERENCE METHODS USED FOR QALYS

TRACK Patient Preference Methods

LEVEL Introductory/Intermediate. This course is for those with some experience with quality of life measures in health economic evaluation.

FACULTY Jan Busschbach, PhD, Chair of Medical Psychology and Psychotherapy, Department of Psychiatry, Erasmus MC, Rotterdam, The Netherlands

COURSE DESCRIPTION During this course, faculty will evaluate the relevant aspects of validity and sensitivity of utility (“quality-adjusted life years or QALY”) assessments, review indirect utility measurement (EQ-5D, SF-36, and the Health Utility Index or HUI), direct utility measurement (standard gamble, time trade-off, and visual analogue scale) and disease-specific utility measurement. Utility measurement, however, is not only about mastering these techniques; it is about using them in such a way that health care decision makers can apply the results, for instance in QALY analyses. For this purpose, one needs to be aware of shortcomings of the available utility measures and potential solutions. Furthermore, one should be aware of the decision-making context and the way that results are interpreted. To equip participants with expertise in the field of utility measurement, the most important issues will be discussed, such as potential insensitivity of generic instruments for particular disease-specific problems and to what extent adaptation of generic- or disease-specific quality of life instruments may offer a solution. This will be demonstrated with practical exercises. Also, the issue of “whos values count: patients or the general public?” will be analyzed. Finally, faculty will turn to interpretation in the context of resource allocation.

BAYESIAN ANALYSIS – OVERVIEW AND APPLICATIONS

TRACK Modeling Methods

LEVEL Introductory/Intermediate.

This course is designed for those with a limited understanding of Bayesian statistical concepts or for those who want a refresher and more practical experience.

FACULTY Christopher S. Hollenbeak, PhD, Associate Professor, Surgery and Public Health Sciences, Penn State College of Medicine, Hershey, PA, USA; Keith R. Abrams, PhD, Professor of Medical Statistics, Department of Health Sciences, University of Leicester, Leicester, UK.

COURSE DESCRIPTION The first portion of this course is designed to provide an overview of the Bayesian approach and its applications to health economics/pharmacoeconomics and outcomes research. The course will cover basic elements of Bayesian statistics, contrasting briefly with classical (frequentist) statistics, and introduce available statistical packages. The second part of the course is a hands-on workshop where participants will be led through a series of exercises using the free Markov Chain Monte Carlo package WinBUGS. Attendees will have the chance to apply the principles they have learned in the morning session to challenging data analysis problems, including the use of Bayesian generalized linear models (GLM) to analyze cost and outcomes data. Participants are encouraged to bring laptops equipped with software provided to course registrants.
COURSE DESCRIPTION Although the number of countries requiring an economic dossier as part of the submission dossier for public reimbursement of new drugs is growing, the pharmaceutical industry cannot conduct economic evaluations in every potential market. However, national decision makers require country-specific or region-specific data or relevant estimates on health care costs and patient outcomes. More and more, they are only willing to accept foreign or international data when transferable to their own decision-making context. However, little guidance exists on how to do this. This course starts with a discussion of factors that make economic data more difficult to transfer from one country to another than clinical data, and will focus on the report of the ISPOR Good Practices on Economic Data Transferability Task Force. In this respect, faculty will discuss the transferability of health state valuations based on the EQ-5D instrument and the transferability of lost productivity data. Next, faculty will review the methods that have been presented to assess the transferability of foreign cost, effects, and cost-effectiveness estimates and their pros and cons. This topic will be practically covered in a case-study while working with your laptop.

TRANSFERABILITY OF COST-EFFECTIVENESS DATA BETWEEN COUNTRIES Brown 3 (L2) TRACK Economic Methods LEVEL Advanced. This course is for those with advanced understanding of economic evaluations of health care programs and experience in the critical assessment of cost-effectiveness studies. FACULTY Silvia Evers, PhD, LLM, Professor of Public Health Technology Assessment, Department of Health Services Research, CAPHRI School for Public Health and Primary Care and Netherlands School of Primary Care Research (Care), Maastricht University, Maastricht, The Netherlands; Manuela Joore, PhD, Associate Professor, Department of Clinical Epidemiology and Medical Technology Assessment, Maastricht University Medical Centre, Maastricht, The Netherlands COURSE DESCRIPTION Although the number of countries requiring an economic dossier as part of the submission dossier for public reimbursement of new drugs is growing, the pharmaceutical industry cannot conduct economic evaluations in every potential market. However, national decision makers require country-specific or region-specific data or relevant estimates on health care costs and patient outcomes. More and more, they are only willing to accept foreign or international data when transferable to their own decision-making context. However, little guidance exists on how to do this. This course starts with a discussion of factors that make economic data more difficult to transfer from one country to another than clinical data, and will focus on the report of the ISPOR Good Practices on Economic Data Transferability Task Force. In this respect, faculty will discuss the transferability of health state valuations based on the EQ-5D instrument and the transferability of lost productivity data. Next, faculty will review the methods that have been presented to assess the transferability of foreign cost, effects, and cost-effectiveness estimates and their pros and cons. This topic will be practically covered in a case-study while working with your laptop.
in small groups. A stepwise procedure will illustrate how to select a foreign cost-effectiveness model for adaptation to your own decision-making context. Finally, a detailed approach on how to adapt a cost-effectiveness model calculation will be illustrated using the case of breast cancer treatment. During the course, faculty will present transferring issues encountered when assessing model-based economic evaluations.

Please note: The statistical methods used to analyze multinational trial data and to transfer these data to a specific country are beyond the scope of this course.

CONJOINT ANALYSIS – THEORY & METHODS 

FACULTY A. Brett Hauber, PhD, Senior Economist & Vice President, Health Preference Assessment, RTI Health Solutions, Research Triangle Park, NC, USA; John F.P. Bridges, PhD, Associate Professor, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

COURSE DESCRIPTION Course participants will learn the conceptual and empirical basis for using conjoint analysis to elicit preferences in outcomes research. The course will introduce participants to both the conceptual basis for quantifying decision-maker preferences for medical interventions and the practical design and analytical issues that must be addressed in order to obtain valid empirical preference estimates. The course will be structured following the good research practice guidelines and discussion prepared by the ISPOR Good Research Practices for the Application of Conjoint Analysis in Health Task Force. The course will include lectures and interactive group exercises and group discussion.

BUDGET IMPACT ANALYSIS I: A 6-STEP APPROACH

FACULTY: Josephine Mauskopf, PhD, Vice President, Health Economics, RTI Health Solutions, Research Triangle Park, NC, USA; C. Daniel Mullins, PhD, Professor & Chair, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, MD, USA; Stephanie Earnshaw, PhD, MS, Vice President, Health Economics, RTI Health Solutions, Research Triangle Park, NC, USA

COURSE DESCRIPTION: This course will describe the methods used to estimate the budget impact of a new health care technology, and will present six basic steps for estimating budget impact: 1) estimating the target population; 2) selecting a time horizon; 3) identifying current and projected treatment mix; 4) estimating current and future drug costs; 5) estimating change in disease-related costs; and 6) estimating and presenting changes in annual budget impact and health outcomes. Both static and dynamic methods for estimating the budget and health impact of adding a new drug to a health plan formulary will be presented. These six steps will be illustrated using actual budget impact models.

RISK-SHARING / PERFORMANCE-BASED ARRANGEMENTS FOR DRUGS AND OTHER MEDICAL PRODUCTS

FACULTY: Adrian Towse, MA, MPhil, Director, Office of Health Economics, London, UK

COURSE DESCRIPTION There is significant and growing interest among the payers and producers of medical products for arrangements that involve a “pay-for-performance” or “risk-sharing” element. These payment schemes involve a plan by which the performance of the product is tracked in a defined patient population over a specified period of time and the level of reimbursement is tied by formula to the outcomes achieved. Although these agreements have an intrinsic appeal, there can be substantial barriers to their implementation. Issues surrounding theory and practice, including incentives and barriers, will be analyzed along with several examples of performance-based schemes from Europe, the United States, and Australia. A hypothetical case study will be used in an interactive session to illustrate a systematic approach to weighing their applicability and feasibility.

Sunday Morning Coffee Break

PHMR sponsored by PHMR

Indicates hands-on exercises requiring the use of your personal computer
provide a key opportunity for attendees to gain exposure to the more practical/ applied aspects of performing budget impact analyses. Participants who wish to gain hands-on experience must bring their laptops with Microsoft Excel for Windows installed.

**DISCRETE EVENT SIMULATION FOR ECONOMIC ANALYSES – APPLICATIONS**

**Amber 2 (L2)**

**TRACK** Modeling Methods

**LEVEL** Intermediate. This course is designed for those with some understanding of discrete event simulation and who wish to have more practical modeling experience.

**PREREQUISITE** Previous attendance at the ISPOR short course “Discrete Event Simulation for Economic Analyses – Concepts,” or equivalent knowledge, is required.

**FACULTY** Jaiame Caro, MDCM, FRCP, FACP, Senior Vice President, Research, Evidera, Lexington, MA; US and Adjunct Professor of Medicine & Adjunct Professor of Epidemiology and Biostatistics, McGill University, Montreal, QC, Canada; Jörgen Möller, MSc, Mech Eng, Vice-President, Modeling, Evidera, Hammersmith, UK and Associate Researcher, Division of Health Economics, Faculty of Medicine, Lund University, Lund Sweden

**COURSE DESCRIPTION** This course is structured around discrete event simulation (DES) exercises. Topics to be covered are: components of a DES, how do you build a model; modeling of processes and resource use; modeling of variables and decisions. Simple animation will be demonstrated. Faculty will guide participants in the use of ARENA to build entry level models. Instructions for downloading training version of ARENA will be distributed prior to the course. Participants who wish to have hands-on experience must bring their personal laptops with ARENA installed.

**NEW! MIXED METHODS APPROACHES FOR PATIENT-CENTERED OUTCOMES RESEARCH: GROUP CONCEPT MAPPING**

**Amber 1 (L2)**

**TRACK** Patient-Reported Outcomes / Preference Methods

**LEVEL** Advanced. This course assumes a basic understanding of qualitative interviewing methods and measurement properties of patient-reported outcomes (PRO) instruments.

**FACULTY** Tara Symonds, PhD, COA Strategy Lead & Partner, Clinical Outcomes Solutions Ltd., Folkestone, UK; Thomas Willgoess, PhD, Project Manager, Clinical Outcomes Assessment, Abacus International, Manchester, UK; Louise Humphrey, MSc, Independent PRO Expert, Manchester, UK; Helen Kitchen, MSc, Consultant, Clinical Outcomes Assessment, Abacus International, Manchester, UK

**COURSE DESCRIPTION** Mixed methods approaches are increasingly acknowledged by both regulatory authorities and the wider scientific community as an important part of the outcomes researcher’s toolkit. Yet there is currently a lack of guidance on how to conduct mixed methods research. This course will guide participants through the different approaches to mixed methods and in particular will expand upon Group Concept Mapping (GCM) – a structured, mixed methods approach ideal for eliciting patient insight into their own disease and treatment experiences and understanding what is most important or burdensome from the patients’ perspective. GCM is a method that can be conducted online and performed in small samples, making it both convenient and cost-effective. Moreover, GCM methodology can be used beyond patient settings and is advocated for use in a diverse range of situations where complex decision making is required and the views of multiple stakeholders must be considered. The benefits and limitations of the innovative GCM approach will be discussed in context of FDA Guidance for Industry – Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims and EMA Reflection Paper on the Regulatory Guidance on the Use of Health-Related Quality of Life (HRQL) Measures in the Evaluation of Medicinal Products. The course will also reference ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modifications PRO Task Force Report. During this short course, participants will take part in a practical exercise giving them real-life experience in conducting and analyzing GCM and allowing them to understand the methodology from the perspective of both a participant and a researcher.

**NETWORK META-ANALYSIS IN RELATIVE EFFECTIVENESS RESEARCH**

**Amber 3-4 (L2)**

**TRACK** Outcomes Research Methods

**LEVEL** Intermediate. This course requires at least a basic knowledge of meta-analysis and statistics.

**FACULTY** Jeroen P. Jansen, MSc, PhD, Founding Partner & Director, Redwood Outcomes, San Francisco, CA, USA; Steve Kanters, MSc, Senior Statistician, Redwood Outcomes and Research Associate, Centre for Clinical Epidemiology and Evaluation, University of British Columbia, Vancouver, BC, Canada

**COURSE DESCRIPTION** For several medical questions of interest, many treatment options exist for the same indication. These treatments may have been compared against placebo or against each other in clinical trials. Knowing whether one specific treatment is better than placebo or some other specific comparator is only a fragment of the big picture, which should incorporate all available information. Ideally, one would know how all the treatment options rank against each other and the level of differences in treatment effects between all the available options. Network meta-analysis provides an integrated and unified method that incorporates all direct and indirect comparative evidence about treatments. Based in part on the ISPOR Task Force Reports on Indirect Treatment Comparisons, the fundamentals and concepts of network meta-analysis will be presented. The evaluation of networks presents special challenges and caveats, which will also be highlighted in this course. The material is motivated by instructive and concrete examples. The ISPOR-AMCP-NPC questionnaire for assessing the credibility of a network meta-analysis will also be introduced.

**PATIENT REGISTRIES**

**Brown 2 (L2)**

**TRACK** Observational Data Methods

**LEVEL** Introductory. This course is designed for those with some or no experience with patient registries.

**FACULTY** Leanne Larson, MHA, Vice President & Global Head, Observational Research, PAREXEL International, Waltham, MA, USA; Angela Vinken, MSc, Senior Director, Observational Research, PAREXEL International, Amsterdam, The Netherlands

**COURSE DESCRIPTION** This course is designed to provide an overview of patient registries and their applications in identifying real world clinical, safety, and patient-perspective issues. The advantages and disadvantages of patient registry versus other real world data collection will be presented. The course will address safety and clinical objectives as well as regulatory trends and requirements. Key operational components, challenges, and measures of program success will be discussed. Management issues, including creating effective partnerships with patient-oriented organizations and facilitating long-term program operations within a changing organizational structure, will be addressed.
NEW! RISK-SHARING/PERFORMANCE-BASED ARRANGEMENTS IN CENTRAL & EASTERN EUROPE: IMPLEMENTATION OF MANAGED ENTRY AGREEMENTS  

**LEVEL** Intermediate.  

**FACULTY** Zoltán Kalá, MSc, MD, PhD, Professor of Health Economics & Head, Institute of Economics, Eötvös Lorand University (ELTE), Budapest, Hungary; Rok Hren, PhD, MSc HUP (HE), Assistant Professor, University of Ljubljana, Ljubljana, Slovenia; Kataryna Kolasa, PhD, Market Access Director Region East, Lundbeck, Warsaw and Poland Department of Health Economics, Collegium Medicum, Bydgoszcz, Poland  

**COURSE DESCRIPTION** During the recent years, Managed Entry Agreements (MEAs) have become instrumental in ensuring the access of the innovative medicines. This course is designed for health care professionals (including public decision-makers, academia and industry) involved in pricing and reimbursement decisions who are wishing to understand the applicability and technical aspects of managed entry agreements (MEAs) in countries with severe economic constraints and explicit cost-effectiveness criterion. The topic will be introduced with key features of pricing and reimbursement systems in Central-Eastern European countries to understand why special methods are needed to facilitate evidence-based reimbursement policies of new health technologies. Faculty will present an economic model to explain the methodology and implications of managed entry agreements in cost-effectiveness and budget impact analysis. Participants will then have the opportunity to apply what they have learned through a hands-on exercise on making pricing and reimbursement decisions. A decision algorithm will be presented to support evidence and value based policy decisions of high-cost new technologies in CEE countries. A series of password protected economic models will add more and more complexity to a pragmatic case study on a new pharmaceutical product in oncology. To close the course faculty will lead a discussion on the applicability of a pragmatic decision tool illustrating the pros and cons of different managed entry agreements and their usefulness in CEE settings. Participants who wish to gain hands-on experience must bring their laptops with Microsoft Excel for Windows installed.

REIMBURSEMENT SYSTEMS FOR PHARMACEUTICALS / BIOLOGICS IN EUROPE  

**TRACK Use of Pharmacoeconomic / Economic / Outcomes Research Information Methods**  

**LEVEL** Intermediate. This course is designed for individuals with intermediate experience within a single health care system wishing to broaden their understanding of other reimbursement systems.  

**FACULTY** Mondher Toumi, MD, PhD, MSc, Professor of Public Health, Aix Marseille University, Marseille, France; Åsa Kornfeld, MSc, Vice-President & Director, Department Pricing, Reimbursement and Market Access, Creativ-Ceutical, Paris, France  

**COURSE DESCRIPTION** Unlike marketing authorization for pharmaceuticals, mainly regulated at the European level by EMA, pricing and reimbursement decisions in Europe are managed by individual member states. Health care services are generally covered by a single public health insurer operating under the Ministry of Health supervision. As a monopoly buyer, this situation provides a leading position for the public health insurer to set reimbursement conditions. Therefore, based on each country’s set of regulations, processes, and values, wide variations exist in pricing and reimbursement decisions of pharmaceuticals. Using up-to-date governmental regulation sources and the ISPOR Global Health Care Systems Roadmap, this course will discuss health technology decision-makings processes for reimbursement decisions for pharmaceuticals in France, Germany, Hungary, Italy, Poland, Spain, Sweden, and the UK. The course will describe these reimbursement systems, as well as compare, and bring into contrast their key characteristics.

NEW! USING MULTI-CRITERIA DECISION ANALYSIS IN HEALTH CARE DECISION MAKING: APPROACHES & APPLICATIONS  

**TRACK Use of Pharmacoeconomic / Economic / Outcomes Research Information Methods**  

**LEVEL** Advanced. Participants should have an understanding of decision analysis.  

**FACULTY** Maarten Uzerman, PhD, Professor Head, Department of Health Technology & Services Research, University of Twente, Enschede, The Netherlands; Kevin Marsh, PhD, Senior Research Scientist, EU Director of Modelling and Simulation, Evidera, London, UK; Nancy Devlin, PhD, Director of Research, Office of Health Economics, London, UK; Praveen Thokala, PhD, MAsc, Research Fellow, School of Health and Related Research (SCHR), University of Sheffield, Sheffield, UK  

**COURSE DESCRIPTION** Many health care decisions such as portfolio optimization, benefit-risk assessment (BRA), health technology assessment (HTA), and shared decision making (SDM) – require a careful assessment of the underlying options and the criteria to used to judge these options. This assessment can be challenging given the tradeoffs between multiple value criteria. In light of this, many decision makers have begun investigating the use of multi-criteria decision analysis (MCDA) in support of these decisions. This course reviews the current MCDA landscape, including a review of MCDA studies in health care and the different approaches employed. Best practices for conducting MCDA will also be outlined, as well as issues related to selecting the right data approach. Steps involved in conducting MCDA (such as criteria definition, scoring performance, weighting criteria, and uncertainty analysis), and current and future applications in health care decision making will be discussed. Faculty will draw from a number of real world examples and will reference the ISPOR Good Practice Guidelines for MCDA. Participants who wish to gain hands-on experience must bring their laptops with Microsoft Excel and Microsoft PowerPoint for Windows installed.

Sunday Afternoon Coffee Break  

Coffee sponsored by Covance
SATURDAY, 7 NOVEMBER

9:00-18:00  PRE-CONGRESS SHORT COURSES  Short Course Registration Required
(See page 18-20 for Short Course descriptions)

13:00-14:00  LUNCH  Attendees on their own, café on L2 will be open to purchase lunch.

18:30-19:30  EDUCATIONAL SYMPOSIUM  Free and open to all delegates, no pre-registration required  Brown 3 (L2)
(See page 69 for Symposium description)
CHALLENGES AND OPPORTUNITIES IN HEART FAILURE: UNMET CLINICAL NEEDS, ECONOMIC BURDEN, AND IMPACT ON SOCIETY
Sponsored by Novartis

SUNDAY, 8 NOVEMBER

8:00-17:00  PRE-CONGRESS SHORT COURSES  Short Course Registration Required
(See page 20-23 for Short Course descriptions)

12:00-13:00  LUNCH  Attendees on their own, café on L2 will be open to purchase lunch.

17:30-18:30  EDUCATIONAL SYMPOSIUM  Free and open to all delegates, no pre-registration required  Brown 3 (L2)
(See page 69 for Symposium description)
BIG DATA, QUICK DATA OR DEEP DATA? INNOVATIVE DESIGNS FOR REAL-WORLD EVIDENCE GENERATION
Sponsored by LASER ANALYTICA

18:45-19:45  EDUCATIONAL SYMPOSIUM  Free and open to all delegates, no pre-registration required  Brown 3 (L2)
(See page 70 for Symposium description)
INNOVATIVE PRICING & THE RELATIONSHIP TO VALUE: STRATEGIC MARKET ACCESS PLANNING & EXECUTION
Sponsored by GalbraithWight

MONDAY, 9 NOVEMBER

7:30-8:30  ISPOR DIAGNOSTICS SPECIAL INTEREST GROUP MEETING (Open to all Attendees)  Amber 1-2 (L2)
All ISPOR Members interested or working in the area of diagnostics are welcome to attend the ISPOR Medical Device and Diagnostic Special Interest Group meeting. This meeting will provide an opportunity for participants to discuss issues and challenges within this field and develop projects to address them.

8:45-14:15  RESEARCH POSTER PRESENTATIONS - SESSION I  South Hall (L0)
(See pages 42-43 for Research Poster Presentations Information)

8:45-10:45  WELCOME & FIRST PLENARY SESSION  Gold (L2)
WELCOME
(See page 86 for Biographical Information)
Daniel Malone, PhD, RPh, 2015-2016 ISPOR President, Professor of Pharmacy, College of Pharmacy, and Associate Professor, Mel & Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA

CONGRESS PROGRAM OVERVIEW
(See page 86 for Biographical Information)
Lorenzo G Mantovani, DSc, Program Committee Co-Chair and Associate Professor of Public Health, Research Centre on Public Health (CESP), University of Milano-Bicocca, Monza, Italy
François Meyer, MD, Program Committee Co-Chair and Advisor to the President, International Affairs, French National Authority for Health (HAS), Saint-Denis La Plaine, France
FIRST PLENARY SESSION: STRATEGY IN MOTION: THE CURRENT AND FUTURE LIFECYCLE APPROACH TO DECISION MAKING ON HEALTH TECHNOLOGIES

Moderator: François Meyer, MD, Advisor to the President, International Affairs, French National Authority for Health (HAS), Saint-Denis La Plaine, France

Speakers:

- Hans-Georg Eichler, MD, MSc, Senior Medical Officer, European Medicines Agency (EMA), London, UK
- Jérôme Boehm, Team Leader, Health Technology Assessment, Directorate-General for Health and Food Safety, European Commission, Brussels, Belgium
- Finn Barlum Kristensen, MD, PhD, Professor, Health Services Research & Health Technology Assessment, University of Southern Denmark and Director, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark
- Mirella Marlow, MA, MBA, Programme Director, Devices and Diagnostics Systems, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), London, UK

10:45-11:15 BREAK, EXHIBITS & RESEARCH POSTER PRESENTATIONS VIEWING - SESSION I South Hall (L0)

(See pages 42-43 for Research Poster Presentations Information)

Coffee sponsored by Truven Health Analytics

11:15-12:15 ISSUE PANELS - SESSION I

(See pages 48-49 for Issue Panel descriptions)

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

IP1: WHAT IS THE ROLE OF ECONOMIC EVALUATION IN PRICING AND REIMBURSEMENT OF MEDICINES? A COMPARISON BETWEEN ENGLAND, GERMANY, AND FRANCE Gold (L2)

Moderator: Wim Goettchis, PhD, Advisor International Affairs, National Healthcare Institute (ZIN), Diemen, The Netherlands

Panelists: Meindert Boysen, PharmD, MSc, Programme Director, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK; Andreas Gerber-Grote, MD, PhD, Head of Health Economics, Institute for Quality and Efficiency in Healthcare (IQWiG), Cologne, Germany; Jean-Luc Harousseau, MD, PhD, President, French National Authority for Health (HAS), Saint-Denis La Plaine, France

IP2: POSSIBLE INCREASED SYNERGY BETWEEN HEALTH TECHNOLOGY ASSESSMENT (HTA) AND REGULATORY AGENCIES: OPPORTUNITY OR CHALLENGE FOR MEDICAL DEVICES? Brown 1-2 (L2)

Moderator: Christopher Henshall, PhD, Associate Professor, Health Economics Research, Brunel University, London, UK

Panelists: Les Levin, MA, MD, Founding Chief Scientific Officer, MaRS EXCITE, Toronto, ON, Canada; François Meyer, MD, Advisor to the President, International Affairs, French National Authority for Health (HAS), Paris, France; Pascale Brasseur, EconD, Chair, HTA Working Group, Eucomed, Brussels, Belgium

IP3: SPEED OR LESS UNCERTAINTY? TRADE-OFFS IN ADAPTIVE PATHWAY IMPLEMENTATION AND POTENTIAL PRICING AND REIMBURSEMENT RESPONSES Brown 3 (L2)

Moderator: Susanne Michel, MD, European Practice Lead, Evidera, London, UK

Panelists: Yvonne-Beatrice Boehler, MD, MBA, Professor for Pharmamanagement, Faculty of Applied Natural Sciences, Cologne University of Applied Sciences, Leverkusen, Germany; Martin Buxton, BA, Emeritus Professor, Health Economics Research Group (HERG), Brunel University, Uxbridge, UK; J Jaime Caro, MDCM, Chief Scientist, Evidera, Lexington, MA, USA

ECONOMIC OUTCOMES RESEARCH ISSUES

IP4: MANAGEMENT OF SPECIALTY DRUGS IN THE UNITED STATES AND EUROPE: ARE WE BALANCING INNOVATION AND AFFORDABILITY? Space 2 (L0)

Moderator: John E. Schneider, PhD, Chief Executive Officer, Avalon Health Economics, Morristown, NJ, USA

Panelists: James Robinson, PhD, Professor, Public Health, University of California, Berkeley, Berkeley, CA, USA; Ansgar Hebborn, PhD, Head - Global HTA & Payment Policy, Global Pricing & Market Access, F. Hoffmann-La Roche AG, Basel, Switzerland

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH ISSUES

IP5: BLOG IT, TWEET IT, LIKE IT, OR BIN IT? THE ROLE OF SOCIAL MEDIA DATA IN PATIENT-REPORTED OUTCOMES RESEARCH Space 1 (L0)

 Moderator: Louise Humphrey, MSc, Director, Abacus International, Manchester, UK

Panelists: Raj Mahapatra, LLB (Hons), Chair, National Ankylosing Spondylitis Society, London, UK; Diana Rofail, PhD, CPsychol, Global Head of Patient-Centered Outcomes Research, Neuroscience and Metabolism, Roche Products Limited, Welwyn Garden City, UK; Thomas G Willgoss, PhD, Project Lead, Clinical Outcomes Assessment, Abacus International, Manchester, UK
**ISPOR 18th Annual European Congress**

7-11 November 2015 | MiCo – Milano Congressi | Milan, Italy

**PROGRAM & SCHEDULE OF EVENTS CONTINUED: MONDAY, 9 NOVEMBER**

12:15-14:15  **LUNCH, EXHIBITS & RESEARCH POSTER PRESENTATIONS VIEWING - SESSION I**  
*South Hall (L0)*

(See pages 42-43 for Research Poster Presentations Information)

Lunch sponsored by RTI Health Solutions

12:30-13:30  **ISPOR STATED-PREFERENCE METHODS SPECIAL INTEREST GROUP MEETING (Open to all Attendees)**  
*Space 1 (L0)*

All ISPOR Members interested or working in the area of Stated-Preference Methods are welcome to attend the ISPOR Stated-Preference Methods Special Interest Group meeting. This meeting will provide an opportunity for participants to discuss issues and challenges within this field and develop projects to address them.

12:45-13:45  **EDUCATIONAL SYMPOSIUM**  
*Free and open to all delegates, no pre-registration required*  
*Gold (L2)*

(See page 72 for Symposium description)

**EMERGING USE OF REAL-WORLD EVIDENCE IN EUROPEAN HEALTH CARE**

Sponsored by Optum

12:45-13:45  **ISPOR STUDENT RESEARCH SHOWCASE**  
*Brown 1-2 (L2)*

**ROLE OF OUTCOMES RESEARCH IMPACTING HEALTH CARE DECISION MAKING – CLOSING THE GAP**

This showcase session will feature four outcomes research studies, conducted by ISPOR student members and presented during the ISPOR 18th Annual European Congress. A brief summary of the research study and conclusions will be presented by each student author followed by a discussion of the role of outcomes research on Impacting Health Decision Making – Closing the Gap.

**Moderators:** Dennis Raisch, PhD, Professor, University of New Mexico, College of Pharmacy, Albuquerque, NM, USA; Zeba M. Khan, PhD, RPh, Vice President, Celgene Corporation, Summit, NJ, USA; Laura Pizzi, PhD, Jefferson University, Philadelphia, PA, USA

**Speakers:** Elisabeth Gargon, BSc, Corporation, Summit, NJ, USA; Joseph F. Stewart, Faculty of Medicine, University of Liverpool, Liverpool, England, United Kingdom; Elisabeth Schafer, MD Candidate, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; Sofie Berghuis, MSc, University of Twente, Enschede, The Netherlands; Jussi P. Repo, University of Helsinki and Helsinki University Hospital, Helsinki, Finland

14:15-14:30  **CA1**  
*Decision in updating the Israeli National List of Health Services*  
*Brown 3 (L2)*

**THE GERMAN NICE OR THE GERMAN NASTY? AN ANALYSIS OF IQWIG DECISIONS AND REQUIREMENTS FOR AN ‘ADDED BENEFIT’**

14:15-14:30  **AG1**

Griffiths EA, HERON Commercialization, London, UK

14:30-14:45  **AG2**  
*Do Evidence Review Groups Bias Nice Decisions?*

14:30-14:45  **Verossa L**, Jaksa A, Liden D, Ho Y, Context Matters, New York, NY, USA

14:45-15:00  **AG3**  
*The Cancer Drugs Fund in England – Undermining Nice or Efficient and Good Value for Money?*

14:45-15:00  **Harries M**, Marshall JD, Stewart D, MAP BioPharma Limited, Cambridge, UK

15:00-15:15  **AG4**  
*Inflation, Inflexibility and Irrelevance – the Need for Inflation to be Accounted for in ICER Thresholds*

15:00-15:15  **Macaulay R**, Udechuku A, PAREXEL, London, UK

**ISPOR STUDENT RESEARCH SHOWCASE**

12:45-13:45  **ISPOR MEDICAL DEVICES SPECIAL INTEREST GROUP MEETING (Open to all Attendees)**  
*Space 1 (L0)*

All ISPOR Members interested or working in the area of medical devices are welcome to attend the ISPOR Value Assessment of Medical Device Working Group meeting to learn more about the group’s current manuscript.

13:15-14:15  **POSTER AUTHOR DISCUSSION HOUR - SESSION I**  
*South Hall (L0)*

(See pages 42-43 for Research Poster Presentations Information)

14:15-15:15  **RESEARCH PODIUM PRESENTATIONS - SESSION I**  
*South Hall (L0)*

(See pages 42-43 for Research Poster Presentations Information)

14:30-15:00  **CA3**  
*Predictors of Positive Decision Outcomes by the Cancer Drugs Fund*

14:30-15:00  **Pearce A**, Hanly P, Sharp I, Soerjomataram I, National Cancer Registry Ireland, Cork, Ireland, National College of Ireland, Dublin, Ireland, Newcastle University, Newcastle, UK, International Agency for Research on Cancer, Lyon, France

15:00-15:15  **CA4**  
*Stereotactic Body Radiation Therapy in Metastatic Prostate Cancer: Clinical Outcomes of a Phase II Trial*

15:00-15:15  **Smith NJ**, Beckerman R, CBPartners, New York, NY, USA, Maple Health Group, LLC, New York, NY, USA
## MEDICAL DEVICE & DIAGNOSTIC RESEARCH STUDIES  Space 2 (L0)

**Moderator:** Giuseppe Turchetti, PhD, Fulbright Scholar Professor of Economics and Healthcare Management, Scuola Superiore Sant’Anna, Pisa, Italy

<table>
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<th>Time</th>
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<tbody>
<tr>
<td>14:00-14:15</td>
<td><strong>MD1</strong> MEDICAL DEVICES: HAVE HEALTH TECHNOLOGY ASSESSMENT AGENCIES STARTED TO FOCUS MORE ON THEM?</td>
</tr>
<tr>
<td>14:15-14:30</td>
<td><strong>MD2</strong> THE COST OF MOLECULAR DIAGNOSTIC TESTING IN ONCOLOGY — A WORKFLOW ANALYSIS</td>
</tr>
</tbody>
</table>

**Notes:**
- **MD1** Le X, Es-Skali IJ, Gubbels IJ, Nijhuis T, Freeman C, Quintiles Advisory Services, Hoofddorp, The Netherlands, Quintiles Advisory Services, Reading, UK
- **MD2** Bellissillo B, Pages J, Collin C, Pasmans R, Montagut C, Department of Pathology, Hospital del Mar, Barcelona, Spain, Laboratoire de Biochimie et Biologie Moleculaire, CHRU Tronseau, Tours, France, Biocartis NV, Mechelen, Belgium, Medical Oncology Department, Hospital del Mar, Barcelona, Spain

**Program & Schedule of Events Continued: Monday, 9 November**

## RESEARCH ON METHODS STUDIES – I  Brown 1-2 (L2)

**Moderator:** Phil McEwan, PhD, Managing Director, Health Economics and Outcomes Research Ltd., Cardiff, UK

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<th>Time</th>
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<tr>
<td>14:00-14:15</td>
<td><strong>PR1</strong> DETERMINANTS OF ORPHAN DRUG PRICES IN FRANCE: REGRESSION ANALYSIS</td>
</tr>
<tr>
<td>14:15-14:30</td>
<td><strong>PR2</strong> PREDICTING POST-AMNOG REBATE OUTCOMES FOR ONCOLOGY DRUGS</td>
</tr>
<tr>
<td>14:30-14:45</td>
<td><strong>PR3</strong> PRICES OF PHARMACEUTICALS UNDER A GENERIC PRICE LINKAGE SYSTEM AND A REFERENCE PRICE SYSTEM: COMPARISON OF AUSTRIA AND FINLAND</td>
</tr>
<tr>
<td>14:45-15:00</td>
<td><strong>PR4</strong> DECISION DRIVERS IN HEALTH TECHNOLOGY ASSESSMENT IN HEPATITIS C</td>
</tr>
</tbody>
</table>

**Notes:**
- **PR2** Subramanian D, Lazarov V, Qiaro Pte. Ltd., Singapore
- **PR3** Maljanen T, Martikainen JE, Koskinen H, Vogler S, Social Insurance Institution, Helsinki, Finland, ‘Austrian Health Institute, Vienna, Austria
- **PR4** Kool-Houweling LM, Kreefte-Mijer J, Van Engen A, Quintiles Advisory Services, Hoofddorp, The Netherlands

## VACCINE STUDIES  Space 3 (L0)

**Moderator:** Baudouin Standaert, MD, PhD, Director, HEOR, GSK Vaccines, Wavre, Belgium

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<tr>
<td>14:15-14:30</td>
<td><strong>VA1</strong> PUBLIC HEALTH IMPACT AND COST-EFFECTIVENESS OF MALARIA ROUTINE VACCINATION IN INFANTS</td>
</tr>
<tr>
<td>14:30-14:45</td>
<td><strong>VA2</strong> COST-EFFECTIVENESS ANALYSIS OF QUADRIVALENT VERSUS TRIVALENT INFLUENZA VACCINATION IN GERMANY — LINKING A DYNAMIC TRANSMISSION MODEL WITH HEALTH AND ECONOMIC OUTCOMES</td>
</tr>
</tbody>
</table>

**Notes:**
- **VA1** Sauboin C, Sicuri E, Van Bellinghen L, Van de Velde N, Van Vlaenderen I, GSK Vaccines, Wavre, Belgium, ‘ISGlobal, Barcelona, Spain, ‘CHESS in Health, Temat, Belgium

## PRICING STUDIES  Space 1 (L0)

**Moderator:** Fulvio Lucchini, PhD, Patient Access Head, Novartis Farma S.p.a., Origgio, Italy

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- **PR4** Kool-Houweling LM, Kreefte-Mijer J, Van Engen A, Quintiles Advisory Services, Hoofddorp, The Netherlands

## PROGRAM & SCHEDULE OF EVENTS CONTINUED: MONDAY, 9 NOVEMBER
15:15-15:45  BREAK & EXHIBITS VIEWING  South Hall (L0)

Coffee sponsored by Truven Health Analytics

15:45-19:45  RESEARCH POSTER PRESENTATIONS - SESSION II  South Hall (L0)

(See pages 42-43 for Research Poster Presentations Information)

15:45-16:00  COST-EFFECTIVENESS STUDIES  Gold (L2)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA339 CE1**

**Basal Insulin Regimens: Systematic Review, Network Meta-Analysis, and Cost – Utility Analysis for the National Institute for Health and Care Excellence (NICE) Clinical Guideline on Type 1 Diabetes Mellitus in Adults**

Dawoud D1, Fenu E1, Wonderling D1, D’Amrony R1, Pursey N2, Cobb J1, Amiel SA1, Higgins B1, National Clinical Guideline Centre, Royal College of Physicians (on behalf of the guideline development group), London, UK, King’s College London, London, UK, Newcastle upon Tyne Hospitals NHS Trust, Newcastle, UK

15:45-16:15  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Maarten J Postma, PhD, Professor, Department of Pharmacy, University of Groningen, Groningen, The Netherlands

**pgA340 CV1**

**The Magnitude of Increased Cardiovascular (CV) Risk Associated with Familial Hypercholesterolemia (FH) for Use in Economic Analyses**

Wong B1, Villa G1, Kutikova L1, Kruse G1, Ray KK1, Mata P1, Bruckert E1, University of Pennsylvania, Philadelphia, PA, USA, Amgen (Europe) GmbH, Zug, Switzerland, School of Public Health, Imperial College London, London, UK, Fundación Hipercolesterolemia Familiar, Madrid, Spain, Hôpital Pitié Salpêtrière, Paris, France

15:45-16:15  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA340 CV2**

**Survival and Readmission After a First Hospitalization for Heart Failure: A Nationwide Population-Based Cohort Study Using the French EGB Database**

Bonnell C1, Millet I1, Achouba A1, Czekala M1, Chauny F1, Thonnellier C1, Husson-Robert C1, Cotin Y1, ORS Bourgogne Franche-Comté, Dijon, France, Novartis Pharma SAS, Rueil-Malmaison, France, ORS Bourgogne Franche-Comté, DIJON, France, CHU Bocage, Dijon, France

15:45-16:15  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA340 CV3**

**The Cost and Length of Stay of Hospital Emergency Department Visits for Chronic Heart Failure Patients in Canada**

Fischer AA1, Liu N1, Borelli R1, Zaour N1, Barreau M1, IMS Brogan, Mississauga, ON, Canada, Novartis Pharmaceuticals Canada Inc., Dorval, QC, Canada

15:45-16:15  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA341 CV4**

**A Review of Patient Registries in Heart Failure Across European Union-5 Countries**

Gupta J1, Sehgal M1, Gupta P2, PAREXEL International, New Delhi, India, PAREXEL International, Chandigarh, India

15:45-16:15  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA341 EA1**

**How Ready are European Payers for EMA Adaptive Pathways?**

Macaulay R1, PAREXEL, London, UK

15:45-16:00  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA341 EA2**

**Access to Innovative Drugs in Patients with Metastatic Lung Cancer in French Public Hospitals (The Territoire Study)**

Scherpereel A1, Fernandez J1, Cottet F2, Blein C2, Debieuvre D3, Durand-Zaleski P1, Gaudin A1, Ozan N1, Saitta B1, Souquet P1, Vainchtock A1, Westeel V1, Chouaid C1, CHU Lille, Lille, France, Oc Santé, Montpellier, France, Bristol-Myers Squibb, Rueil-Malmaison, France, HEVA, Lyon, France, Mulhouse Hospital, Mulhouse, France, URCE Eco, Paris, France, Besançon Hospital, Besançon, France, CHIC, Créteil, France

15:45-16:15  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA341 EA3**

**The Economic Impact of an Hypothetical Rx-to-OTC Switch in Spain**

Pellise L1, Serra M1, Universitat Pompeu Fabra, Barcelona, Spain

15:45-16:30  Cardiovascular Disease Research Studies  Space 2 (L0)

Moderator: Paolo Angelo Cortesi, PhD, Researcher, Research Centre on Public Health (CESP), Milano-Bicocca, Monza, Italy

**pgA341 EA4**

**Orphan Designations and Approvals in the EU, United States and Japan**

USE OF REAL WORLD DATA

F1: RARE DISEASE CLINICAL TRIALS - EMERGING GOOD PRACTICES FOR CLINICAL OUTCOMES ASSESSMENT OUTCOMES (PROS, CLINROS & OBSROS) MEASUREMENT - GOLD (L2)

Presented by the ISPOR COA Measurement in Rare Disease Clinical Trials – Emerging Good Practices Task Force
Moderator: Margaret K. Vernon, PhD, Senior Research Scientist, Evidera, London, UK
Speakers: Donald L. Patrick, PhD, MSPH, Professor, Department of Health Services and Director, Seattle Quality of Life Group and Biobehavioral Cancer Prevention and Training Program, University of Washington, Seattle, WA, USA; Eleanor M. Perfetto, PhD, MS, Professor, Pharmaceutical Health Services Research, University of Maryland, Baltimore, MD, USA and Senior Vice President, Strategic Initiatives, National Health Council, Washington, DC, USA

F2: MAPPING TO ESTIMATE UTILITY VALUES FOR COST PER QALY ECONOMIC ANALYSIS - GOOD RESEARCH PRACTICES - BROWN (L2)

Presented by the Mapping to Estimate Health State Utility Values from Non-Preference Based Outcomes Measures for Cost per QALY Economic Analysis Good Research Practices Task Force
Moderator/Speaker: Allan J Wailoo, PhD, Professor of Health Economics, ScHARR, University of Sheffield and Director, NICE Decision Support Unit, Sheffield, UK
Speaker: Joshua Ray, MSc, Head of Health Economics Modelling, F. Hoffman-La Roche, Basel, Switzerland

F3: MEDICAL NUTRITION – TERMS, DEFINITIONS, REGULATIONS & EMERGING GOOD PRACTICES FOR ECONOMIC EVALUATION - BROWN 1-2 (L2)

Moderator: Karen Freyer, PhD, Nutritionist & Nutrition Economist, School for Public Health and Primary Care (CAPHRI), Maastricht University, Zoetermeer, The Netherlands
Speakers: Sheri Volger, MS, Principal Clinical Scientist, Nestlé Nutrition R&D, King of Prussia, PA, USA; Oznur Seyhun, MSc, MFE, Senior Market Access Manager, Abbott Nutrition, Istanbul, Turkey; Josephine Mauskopf, PhD, Vice President, Health Economics, RITI Health Solutions, Research Triangle Park, NC, USA

F4: HEALTH TECHNOLOGIES PRICING AND DECISION MAKING IN THE CENTRAL SOUTH EUROPE: WHAT, WHERE, WHEN, AND HOW? - SPACE 2 (L2)

Presented by the ISPOR CEE Network
Moderator: Tomas Doelezal, MD, PhD, President, ISPOR Czech Chapter and Director, iHEA, Prague, Czech Republic
Speakers: Mary Geitona, MSc, PhD, Professor, University of Peloponnese, Athens, Greece; Malwina Holownia, MPHarm, Director of Economics, Russian Society for Pharmacoconomics and Outcomes Research, Moscow, Russia; Pero Draganic, MD, PhD, Assistant Professor, Principal Advisor for Safe Use of Medicines, HALMED, Croatian Agency for Medicinal Products and Medical Devices, Zagreb, Croatia; Bertalan Nemeth, MSc, Senior Health Economist, Syreon Research Institute, Budapest, Hungary

F5: PARALLEL TRADE: CAN WE CURB THE IMPACT ON CENTRAL & EASTERN EUROPEAN (CEE) COUNTRIES? - SPACE 1 (L0)

Presented by the ISPOR CEE Network
Moderator: Joanna Lis, PhD, President, ISPOR Poland Chapter, Adjunct Professor, Pharmacoconomics Department, Medical University of Warsaw, and Director, Market Access, Sanofi, Warsaw, Poland
Speakers: Jana Skoupa, MD, MBA, Researcher, Charles University, Prague, Czech Republic; Zoran Sterjev, PharmD, PhD, Assistant Professor, Faculty of Pharmacy, UKIM-Skopje, Skopje, Macedonia; Natalia Bogavac-Stanojevic, PhD, Assistant Professor, Faculty of Pharmacy, University of Belgrade, Belgrade, Serbia; Assena Stoitomenova, PhD, Associate Professor and Executive Director, The Bulgarian Drug Agency, Sofia, Bulgaria
F6: BUDGET RESTRICTIONS FOLLOWING THE ECONOMIC CRISIS: THREATS OR OPPORTUNITIES FOR THE DEVELOPMENT OF ECONOMIC EVALUATION IN THE SOUTHERN EUROPEAN REGION  

Space 3 (L0)

Presented by the ISPOR Regional Chapters in Greece, Italy-Milan, Italy-Rome, Portugal, and Spain

Moderator: Lorenzo Mantovani, DSc, President, ISPOR Italy-Milan Chapter and Associate Professor of Public Health, Research Centre on Public Health (CESP), University of Milano-Bicocca, Monza, Italy

Speakers: Carlos Gouveia Pinto, PhD, President, ISPOR Portugal Chapter and President, Research Center on the Portuguese Economy (CISEP), School of Economics & Management, University of Lisbon, Lisbon, Portugal; Carme Pinyol, MD, MSc, Founder & Director, INNOVA -Strategic Consulting, Barcelona, Spain; Americo Cicchetti, DSc, Professor of Management and Healthcare Management & Director, Graduate School of Health Economics and Management, Catholic University of Sacred Heart (ALTEM), Rome, Italy; John Yfantopoulos, PhD, President, ISPOR Greece Chapter and Professor of Health Economics, School of Economics and Political Science, University of Athens, Athens, Greece

18:45-19:45  POSTER AUTHOR DISCUSSION HOUR - SESSION II  South Hall (L0)

(See pages 42-43 for Research Poster Presentations Information)

19:45-21:00  ISPOR STUDENT WELCOME RECEPTION  Gold View Lounge (L2)

All students and faculty are welcome to attend! One of the main goals of the ISPOR Student Network is to increase the connection among student members and faculty. Please join us this year to continue the success and increase your networking connections!

19:45-21:00  ISPOR CENTRAL & EASTERN EUROPE (CEE) NETWORK WELCOME RECEPTION  Panorama Lounge (L3)

A great opportunity to meet & network with ISPOR colleagues from the CEE region! All attendees interested in the Network, its organization, activities and current initiatives are welcome to attend. ISPOR CEE Network includes members from ISPOR Regional Chapters in Central & Eastern Europe. For more information visit www.ispor.org >> Regional Chapters/Networks >> ISPOR Networks Index >> CEE Network. To find out how to get involved, please send an email to: ceenet@ispor.org

TUESDAY, 10 NOVEMBER

7:00-8:30  ISPOR RARE DISEASE SPECIAL INTEREST GROUP MEETING (Open to all Attendees)  Amber 3-4 (L2)

All ISPOR Members interested or working in the area of the Health Technology Assessment (HTA) of rare diseases are welcome to attend the ISPOR Rare Disease Special Interest Group meeting. This meeting will provide an opportunity for participants to discuss issues and challenges within the rare disease and HTA field.

7:30-8:30  UPDATING ISPOR VISION 2020  Brown 1-2 (L2)

Join ISPOR’s President, Daniel Malone, CEO, Nancy Berg, and other Board Members to learn about updates to ISPOR’s Vision 2020, the Society’s strategic plan. Coffee and pastries will be served.

7:30-8:30  EDUCATIONAL SYMPOSIUM  Free and open to all delegates, no pre-registration required  Brown 3 (L2)

(See page 72 for Symposium description)

NEW APPROACHES TO CAPTURING VALUE IN ONCLOGY

Sponsored by Bristol-Myers Squibb

8:45-13:45  RESEARCH POSTER PRESENTATIONS - SESSION III  South Hall (L0)

(See pages 42-43 for Research Poster Presentations Information)

8:45-9:45  WORKSHOPS - SESSION II

(See pages 57-58 for Workshop descriptions)

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

W7: MARKET ACCESS 2020: WHAT ARE THE NEXT CHALLENGES?  Gold (L2)

Discussion Leaders: Meriem Bouslouk, PhD, MSc, Officer, Pharmaceuticals Department, Federal Joint Committee (G-BA), Berlin, Germany; Jan Mueller-Berghaus, MD, Paul-Ehrlich- Institute (PEI), Langen, Germany; Antoni Gilabert-Perramon, PhD, Managing Director of Pharmacy and Medicines, Catalan Health Service, Government of Catalonia, Barcelona, Spain; Mondher Toumi, MD, MSc, PhD, Professor of Public Health, Department of Public Health, Aix-Marseille University, Marseille, France

W8: EVIDENCE SYNTHESIS BASED ON AGGREGATE AND INDIVIDUAL-LEVEL DATA: CONSIDERATIONS FOR USE IN HTA DECISION MAKING  Brown 3 (L2)

Discussion Leaders: Timothy Reason, MSc, Senior Consultant, Real-world Evidence Solutions, IMS Health, London, UK; Pedro Saramago Goncalves, MSc, PhD, Research Fellow, Centre of Health Economics, University of York, Heslington, York, UK; Yumi Asukai, MSc, Director, R&D Value Evidence Analytics, GSK, Uxbridge, UK; Keith Abrams, PhD, Professor of Medical Statistics, Department of Health Sciences, University of Leicester, Leicester, UK

USE OF REAL WORLD DATA

W9: DEVELOPMENT OF EVIDENCE PACKAGES FOR REGULATORY AND REIMBURSEMENT SUBMISSIONS IN RARE DISEASES: REAL-WORLD EXAMPLES  

Space 1 (L0)

Discussion Leaders: Nicola Bonner, MSc, Senior Research Manager, EDOA, Adelphi Values Ltd, Bollington, UK; Alexandra Bowden, PhD, Senior Manager, Ultragenyx Pharmaceutical Inc., Novato, CA, USA; Vasudha Bal, MSc, MBA, Director, Patient Reported Outcomes, Worldwide Health Outcomes, Value & Access, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; Anne Kilburg, MSc, Principal Consultant, Wellmera AG, Basel, Switzerland
ISPOR 18th Annual European Congress
7-11 November 2015 | MiCo – Milano Congressi | Milan, Italy

PROGRAM & SCHEDULE OF EVENTS CONTINUED: TUESDAY, 10 NOVEMBER

CLINICAL OUTCOMES RESEARCH

W10: MOVING THE SCIENCE FORWARD: TACKLING KEY PSYCHOMETRIC AND METHODOLOGICAL ISSUES FACING THE FIELD OF CLINICAL OUTCOME ASSESSMENT  
Space 2 (L0)

Discussion Leaders: Tara Symonds, PhD, COA Strategy Lead & Partner, Clinical Outcomes Solutions Ltd., Folkestone, Kent, UK; Kathleen W. Wyrwich, PhD, Executive Director, Center of Excellence, Outcomes Research, Evidera, Bethesda, MD, USA; Antoine Regnault, PhD, Research Director, HEOR & Strategic Market Access, Mapit, Lyon, France; Stephen Joel Coons, PhD, Executive Director, PRO Consortium, Critical Path Institute, Tucson, AZ, USA

ECONOMIC OUTCOMES RESEARCH

W11: TRANSLATING PHARMACOMETRICS TO PHARMACOECONOMICS  
Space 3 (L0)

Discussion Leaders: Richard J. Willke, PhD, Vice President, Outcomes & Evidence Lead CV/Metabolic, Pain, Urology, Gender Health, Global Health & Value, Pfizer Inc., New York, NY, USA; Scott Marshall, PhD, Senior Director, Pharmacometrics, Global Clinical Pharmacology, Pfizer, Inc., Sandwich, UK; John Posnett, DPhil, Vice President, Health Economic Modelling Unit, PAREXEL International, London, UK; Julia F Sleijko, PhD, Assistant Professor, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, MD, USA

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH

W12: OPTIMIZING PATIENT INVOLVEMENT IN PAYER HEALTH CARE DECISIONS TO ACCESS NEW THERAPIES  
Brown 1-2 (L2)

Discussion Leaders: Nicola Bedlington, Director, European Patients’ Forum, Brussels, Belgium; Michael Barry, MD, PhD, Clinical Director, National Centre for Pharmacoeconomics, Dublin, Ireland; Bettina Ryll, PhD, Director, European Patients’ Forum, Brussels, Belgium; Veronica Foote, BA, Head of Patient Relations & External Communications, Novartis Oncology Europe, Surrey, UK

9:45-10:15  BREAK, EXHIBITS & RESEARCH POSTER PRESENTATIONS VIEWING - SESSION III  
South Hall (L0)

(See pages 42-43 for Research Poster Presentations Information)

Coffee sponsored by Optum

10:15-12:00  WELCOME & SECOND PLENARY SESSION  
Gold (L2)

WELCOME

(See page 86 for Biographical Information)
Daniel Malone, PhD, RPh, 2015-2016 ISPOR President, Professor of Pharmacy, College of Pharmacy, and Associate Professor, Mel & Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA

2015 ISPOR AVEDIS DONABEDIAN OUTCOMES RESEARCH LIFETIME ACHIEVEMENT AWARD

(See page 89 for Biographical Information)

Presented by: Mark J. Sculpher, MSc, PhD, Chair, ISPOR Avedis Donabedian Lifetime Achievement Award in Health Outcomes Committee and Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK

AWARDEE: Anthony John (Tony) Culyer, CBE, BA, Hon Decon, Hon FRCP, FRSA, FMedSci, Emeritus Professor of Economics, University of York, UK

ISPOR AWARD FOR 2015 VALUE IN HEALTH PAPER OF THE YEAR

(See page 90 for Biographical Information)

Presented by: Michael Drummond, MCom, DPhil, University of York, Heslington, York, UK, and C. Daniel Mullins, PhD, University of Maryland, Baltimore, MD, USA, Value in Health Co-Editors-in-Chief

AWARDEE: Lucas M.A. Goossens, PhD, Assistant Professor, Erasmus University, Institute for Health Policy & Management, Rotterdam, The Netherlands

ISPOR AWARD FOR 2015 VALUE IN HEALTH REGIONAL ISSUES EXCELLENT ARTICLE

(See page 90 for Biographical Information)

Presented by: Dan Greenberg, PhD, Value in Health Regional Issues Co-Editor-in-Chief (CEEWAA) and Associate Professor, Department of Health Systems Management, Faculty of Health Sciences & Guilford Glazer Faculty of Business and Management, Ben-Gurion University of the Negev, Be’er Sheva, Israel

AWARDEE: Rok Hren, PhD, MSc, IHP (NE), Assistant Professor, University of Ljubljana, Ljubljana, Slovenia

SECOND PLENARY SESSION: OUTCOMES RESEARCH: ARE WE READY TO PUT THEORY INTO PRACTICE?

(See pages 87-89 for Biographical Information)

In the last four decades, the assessment of outcomes has been moving from the mere ground of research into daily practice. This session will provide researchers and policy makers with an update on current practices, challenges, opportunities, and future perspectives on the assessment of outcomes in different fields of health care: reimbursement of drugs and devices, evaluation of public health interventions, validation of new technologies, and financing of complex health services.

Moderator: Lorenzo G Mantovani, DSc, Associate Professor of Public Health, Research Centre on Public Health (CESP), University of Milano-Bicocca, Monza, Italy
Program & Schedule of Events Continued: Tuesday, 10 November

Speakers:
Brian O’Rourke, PharmD, President & Chief Executive Officer, Canadian Agency for Drugs and Technologies in Health (CADTH), Ottawa, ON, Canada
Sergio Pecorelli, MD, PhD, Chairman of the Board, Italian Medicines Agency (AIFA) and Professor, Department of Obstetrics and Gynecology, & Chancellor, University of Brescia, Brescia, Italy
Mario Strazzabosco, MD, PhD, Deputy Director, Yale Liver Center & Section of Digestive Diseases, Department of Internal Medicine, Yale University School of Medicine and Director, Department of Surgical and Interdisciplinary Medicine, University of Milano-Bicocca, Monza, Italy
Walter Ricciardi, Past-President, European Public Health Association (EUPHA) and Professor & Director, Department of Public Health, Catholic University of the Sacred Heart, Rome, Italy

12:00-13:45 LUNCH, EXHIBITS & RESEARCH POSTER PRESENTATIONS VIEWING - SESSION III South Hall (L0)
(See pages 42-43 for Research Poster Presentations Information)
Lunch Sponsored by BaseCase

12:15-13:30 ISPOR ONCOLOGY SPECIAL INTEREST GROUP MEETING (Open to all Attendees) Space 3 (L0)
All ISPOR Members interested or working in oncology are welcome to attend the ISPOR Oncology Special Interest Group meeting. This meeting will provide an opportunity for participants to discuss and develop upcoming projects the Working Group is undertaking.

12:30-13:30 EDUCATIONAL SYMPOSIUM Free and open to all delegates, no pre-registration required Gold (L2)
(See page 73 for Symposium description)
RARE DISEASES: NAVIGATING THE ROAD TO APPROVAL AND ACCESS
Sponsored by RTI Health Solutions

12:45-13:45 POSTER AUTHOR DISCUSSION HOUR - SESSION III South Hall (L0)
(See pages 42-43 for Research Poster Presentation Information)

13:45-14:45 ISSUE PANELS - SESSION II
(See pages 49-51 for Issue Panel descriptions)

Health Policy Development Using Outcomes Research Issues
IP6: ASSESSMENT OF THE VALUE OF MEDICAL DEVICES: CAN WE SIMPLY APPLY PROCESSES ESTABLISHED FOR DRUGS OR DO WE NEED TO PURSUE SEPARATE PROCESSES FOR DEVICES? Brown 1-2 (L2)
Moderator: Wolfgang Greiner, PhD, Head, Department for Health Economics and Health Care Management, School of Public Health, Bielefeld University, Bielefeld, Germany
Panelists: Thomas Mittendorf, PhD, Managing Director & Vice President, Xcenda GmbH, Hannover, Germany; Ron Akehurst, PhD, Strategic Director, BresMed Health Solutions Ltd, Sheffield, UK; Alric Ruether, MD, PhD, Head, Department of Health Care Quality, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany

IP7: ARE CURRENT ICER THRESHOLDS OUTDATED? DOES MCDA OFFER A MORE HOLISTIC APPROACH TO ASSESSING THE VALUE OF INNOVATIVE TECHNOLOGIES? Space 1 (L0)
Moderator: Zeba M. Khan, RPh, PhD, Vice President, Celgene Corporation, Summit, NJ, USA
Panelists: John Proach, MBA, Executive Vice President, Pricing and Market Access, Market Access Solutions LLC, Raritan, NJ, USA; Andrew Briggs, DPhil, MSc, William R. Lindsay Professor of Health Economics, Department of Health Economics & Health Technology Assessment, Institute of Health & Wellbeing, University of Glasgow, Glasgow, UK; Maarten J. Ijzerman, PhD, Professor of Clinical Epidemiology & HTA & Vice Dean, Health & Biomedical Technology, Faculty of Science & Technology, University of Twente, Enschede, The Netherlands

IP8: THE COST OF NO EUROPE: ARE THERE COSTS AND CONSEQUENCES OF LOCALIZED OR CENTRALIZED ASSESSMENT OF RELATIVE EFFICACY? Gold (L2)
Moderator: Alastair Kent, OBE, Director, Genetic Alliance UK, London, UK
Panelists: Andrea Rappagliosi, LLM, Vice President, Market Access, Health Policy and Medical Affairs, Sanofi Pasteur MSD, Lyon, France; Carole Longson, PhD, Director, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK; Jacco Keja, PhD, Senior Principal, Real-World Evidence Solutions & HEOR, IMS Health, London, UK and Lecturer, RWES, IMS Health, Rotterdam, The Netherlands

Clinical Outcomes Research Issues
IP9: IS A SINGLE EVIDENCE BASE POSSIBLE ACROSS EUROPE? HOW SHOULD EVIDENCE GENERATION EFFORTS BE FOCUSED TO MEET PAYER REQUIREMENTS FOR MARKET ACCESS? Space 2 (L0)
Moderator: Ad Rietveld, MD, MBA, Director, RIW & Partners, Royston, UK
Panelists: Wil Toenders, MSc, Consultant, ToendersdeGroot, Utrecht, The Netherlands; Bernard Avouac, MD, Former President, Transparency Commission, Paris, France; Wolfgang Kaesbach, PhD, Former Head, National Association of Statutory Health Insurance Funds (GKV), Berlin, Germany

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ISPOR 18th Annual European Congress
7-11 November 2015 | MiCo – Milano Congressi | Milan, Italy

PROGRAM & SCHEDULE OF EVENTS CONTINUED: TUESDAY, 10 NOVEMBER

ECONOMIC OUTCOMES RESEARCH ISSUES

IP10: QUALITY-ADJUSTED LIFE YEARS (QALYS) – HELP OR HINDRANCE IN SUPPORTING HEALTH CARE DECISION MAKING? Brown 3 (L2)
Moderator: Emelie Maria Heintz, PhD, Health Economist, Swedish Council on Health Technology Assessment (SBU), Stockholm, Sweden
Panelists: Mark J. Sculpher, MSc, PhD, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; Ariel Beresniaik, MD, MPH, PhD, Chief Executive Officer, Data Mining International, Geneva, Switzerland; Irina Cleemput, PhD, MSc, Senior Health Economist, Belgian Health Care Knowledge Institute (KCE), Brussels, Belgium

14:45-15:15 BREAK & EXHIBITS VIEWING South Hall (L0)
Coffee sponsored by Optum

15:15-18:15 RESEARCH POSTER PRESENTATIONS - SESSION IV South Hall (L0)
(See pages 42-43 for Research Poster Presentations Information)

15:15-16:15 ISSUE PANELS - SESSION III
(See pages 51-52 for Issue Panel descriptions)

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

IP11: BUILDING LIGHT HTA APPROACH IN CENTRAL AND EASTERN EUROPEAN COUNTRIES BASED ON HTA RECOMMENDATIONS IN WESTERN EUROPEAN COUNTRIES: MORE HARM THAN GOOD? Gold (L2)
Moderator: Finn Berlum Kristensen, MD, PhD, Professor, Health Services Research & Health Technology Assessment, University of Southern Denmark and Director, EUReHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark
Panelists: Katarzyna Kolasa, PhD, Market Access Director, Oy H. Lundbeck Ab, Turku, Finland; Mirjana Huic, MD, PhD, Assistant Director, Department for Development, Research and Health Technology Assessment, Agency for Quality and Accreditation in Health Care and Social Welfare, Zagreb, Croatia; Zoltán Kaló, PhD, Professor of Health Economics, Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary

IP12: WHAT ARE THE OPPORTUNITIES AND CHALLENGES IN DEVELOPING TRANSPARENCY OF CLINICAL (TRIAL) DATA? Brown 1-2 (L2)
Moderator: Meinert Boysen, PharmD, MSc, Programme Director, Centre for Health Technology Evaluation, National Institute for Health and Clinical Excellence (NICE), Manchester, UK
Panelists: Noel Wateron, PharmD, Chief Policy Adviser, European Medicines Agency (EMA), London, UK; Richard Bergstrom, PharmD, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium; Beate Wieseler, PhD, Head of Drug Assessment, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany

USE OF REAL WORLD DATA ISSUES

IP13: BEST AVAILABLE EVIDENCE FOR HEALTH TECHNOLOGY ASSESSMENT DECISION MAKING: EFFICACY OR EFFECTIVENESS? Space 1 (L0)
Moderator: Robert B McQueen, PhD, Health Economist, Research in Real Life (RiRL), Cambridge, UK
Panelists: Jonathan D. Campbell, PhD, Assistant Professor, Center for Pharmaceutical Outcomes Research, University of Colorado Anschutz Medical Campus, Denver, CO, USA; Piyameth Dilokthornsakul, PharmD, Doctor, Center of Pharmaceutical Outcomes Research, Naresuan University, Muang, Phitsanulok, Thailand; David Price, MD, Professor of Primary Care Respiratory Medicine, Division of Applied Health Sciences, University of Aberdeen, Aberdeen, UK

ECONOMIC OUTCOMES RESEARCH ISSUES

IP14: VALUING HEALTH: HAVE WE REALLY GOT IT RIGHT? Space 2 (L0)
Moderator: Pauline McNulty, Vice President, Patient Reported Outcomes, JGS USA Janssen Global Services, Johnson & Johnson, Raritan, NJ, USA
Panelists: Paul Kind, Professor, Centre for Health Economics, Management and Policy, HSE University, St Petersburg, Russia; Ben van Hout, Professor, School of Health and Related Research (ScHARR), The University of Sheffield, Sheffield, UK

IP15: THE TRUTH, THE WHOLE TRUTH, AND NOTHING BUT THE TRUTH: SHOULD WE STICK TO PRAGMATIC INCREMENTALISM OR IS IT TIME TO TAKE COST-EFFECTIVENESS ANALYSES UP TO THE LEVEL OF DISEASE MODELLING? Brown 3 (L2)
Moderator: Margreet Franken, PhD, Scientific Researcher, Institute for Medical Technology Assessment (iMTA), Rotterdam, The Netherlands
Panelists: Michel van Aagtoven, PhD, Head of Market Access, GILEAD Sciences, Amsterdam, The Netherlands; Saskia Knes, PhD, Policy Advisor Health Economics, National Health Care Institute (ZiN), Dieren, the Netherlands; Carin Uyl-de Groot, PhD, Professor Health Technology Assessment, Institute for Medical Technology Assessment (iMTA), Rotterdam, The Netherlands

16:30-17:30 WORKSHOPS - SESSION III
(See pages 59-60 for Workshop descriptions)

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

W13: THE ROLE OF VALUE OF INFORMATION IN HTA: ARE WE MISSING AN OPPORTUNITY? Brown 3 (L2)
Discussion Leaders: Gianluca Bai, PhD, Reader in Statistics & Health Economics, Statistical Science, University College London, London, UK; Nicky J. Welton, MSc, PhD, Reader in Evidence Synthesis, School of Social and Community Medicine, University of Bristol, Bristol, UK; Mark Strong, PhD, Clinical Senior Lecturer in Public Health, School of Health and Related Research, University of Sheffield, Sheffield, UK; Anna Heath, BSc, PhD Student, Statistical Science, University College London, London, UK
Panelists: Michel van Aagtoven, PhD, Head of Market Access, GILEAD Sciences, Amsterdam, The Netherlands; Saskia Knes, PhD, Policy Advisor Health Economics, National Health Care Institute (ZiN), Dieren, the Netherlands; Carin Uyl-de Groot, PhD, Professor Health Technology Assessment, Institute for Medical Technology Assessment (iMTA), Rotterdam, The Netherlands

W14: ORPHAN DRUG EVIDENCE REQUIREMENTS FOR POSITIVE HTA RECOMMENDATIONS Gold (L2)
Discussion Leaders: Josie Godfrey, MA, Associate Director, Highly Specialised Technologies, National Institute for Health and Care Excellence (NICE), London, UK; François Meyer, MD, Advisor to the President, International Affairs, French National Authority for Health (HAS), Paris, France; Mondher Toumi, MD, MSc, PhD, Professor of Public Health, Department of Public Health, Aix-Marseille University, Marseille, France; Meriem Bouslouk, PhD, MSc, Officer, Pharmaceuticals Department, Federal Joint Committee (G-BA), Berlin, Germany
USE OF REAL WORLD DATA

W15: SAMPLE SIZE ESTIMATION AND POWER CALCULATION FOR PROSPECTIVE OBSERVATIONAL STUDIES  Space 2 (L0)
Discussion Leaders: Eric Gemmen, MA, Senior Practice Leader, Epidemiology & Outcomes Research, Real-World & Late Phase Research, Quintiles, Inc., Rockville, MD, USA; Mark J Nixon, MS, PhD, Director, Chilli Consultancy, Salisbury, UK

W16: RETROSPECTIVE HEALTH OUTCOMES RESEARCH AND HEALTH-ECONOMIC EVALUATION BASED ON REAL-WORLD DATA ANALYSES IN EUROPE: DATA AVAILABILITY, STRENGTHS AND LIMITATIONS, AND DATABASE-SPECIFIC CONSIDERATIONS  Space 3 (L0)
Discussion Leaders: Thomas Wilke, MD, Partner, Ingress-Health, Wismar, Germany; Myrthe P. P. van Herk-Sukel, PhD, Manager, Research Department & Epidemiologist, PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands; Andreas Fuchs, PhD, Consulting Pharmacist, AOK PLUS, Dresden, Germany; Wilhelmine Meeraus, MSc, Research Scientist, Medicines and Healthcare Products Regulatory Agency, The Clinical Practice Research Datalink, London, UK

ECONOMIC OUTCOMES RESEARCH

W17: CHALLENGES AND SOLUTIONS TO SUCCESSFULLY DETERMINE REAL-WORLD COST-EFFECTIVENESS  Space 1 (L0)
Discussion Leaders: Saskia de Groot, MSc, Researcher, Institute of Health Policy & Management, Institute for Medical Technology Assessment (iMTA), Erasmus University Rotterdam, Rotterdam, The Netherlands; Hedwig M. Blommestein, MSc, Researcher, Institute of Health Policy & Management, Institute for Medical Technology Assessment (iMTA), Erasmus University Rotterdam, Rotterdam, The Netherlands; Margreet G. Franken, PhD, Researcher, Institute for Medical Technology Assessment (iMTA), Erasmus University Rotterdam, Rotterdam, The Netherlands; Annet F.M. van Abeelen, PhD, Pharmaco Economics & Access Manager, Health Economics and Business Development, Roche Pharmaceuticals Netherlands, Woerden, The Netherlands

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH

W18: UTILITIES IN HTA: CHALLENGES FOR THEORY AND PRACTICE NOW AND IN THE FUTURE  Brown 1-2 (L2)
Discussion Leaders: Jenny Berg, PhD, Senior Scientist, Map, Stockholm, Sweden; Nancy Devlin, PhD, Director of Research, Office of Health Economics, London, UK; Michael Drummond, MCom, DPhil, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; Karin G. M. Groothuis-Oudshoorn, PhD, Assistant Professor, Health Technology and Services Research, University of Twente, Enschede, The Netherlands; John F.P. Bridges, PhD, Associate Professor, Department of Health Policy and Management and International Health, John Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; John J. Ijzerman, PhD, Senior Scientist, Mapi, Stockholm, Sweden; Annet F.M. van Abeelen, PhD, Pharmaco Economics & Access Manager, Health Economics and Business Development, Roche Pharmaceuticals Netherlands, Woerden, The Netherlands; Michael Drummond, MCom, DPhil, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK

W19: SAMPLE SIZE ESTIMATION AND POWER CALCULATION FOR PROSPECTIVE OBSERVATIONAL STUDIES  Space 2 (L0)
Discussion Leaders: Eric Gemmen, MA, Senior Practice Leader, Epidemiology & Outcomes Research, Real-World & Late Phase Research, Quintiles, Inc., Rockville, MD, USA; Mark J Nixon, MS, PhD, Director, Chilli Consultancy, Salisbury, UK

W20: RETROSPECTIVE HEALTH OUTCOMES RESEARCH AND HEALTH-ECONOMIC EVALUATION BASED ON REAL-WORLD DATA ANALYSES IN EUROPE: DATA AVAILABILITY, STRENGTHS AND LIMITATIONS, AND DATABASE-SPECIFIC CONSIDERATIONS  Space 3 (L0)
Discussion Leaders: Thomas Wilke, MD, Partner, Ingress-Health, Wismar, Germany; Myrthe P. P. van Herk-Sukel, PhD, Manager, Research Department & Epidemiologist, PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands; Andreas Fuchs, PhD, Consulting Pharmacist, AOK PLUS, Dresden, Germany; Wilhelmine Meeraus, MSc, Research Scientist, Medicines and Healthcare Products Regulatory Agency, The Clinical Practice Research Datalink, London, UK

F7: CONJOINT ANALYSIS: GOOD RESEARCH PRACTICES FOR STATISTICAL ANALYSIS  Brown 3 (L2)
Presented by the ISPOR Conjoint Analysis Good Research Practices Task Force
Moderator: A. Brett Hauber, PhD, Senior Economist & Vice President, Health Preference Assessment, RTI Health Solutions, Research Triangle Park, NC, USA
Speakers: Maarten J. Uzerman, PhD, Professor of Clinical Epidemiology & Health Technology Assessment (HTA) and Head, Department of Health Technology & Services Research, University of Twente, Enschede, The Netherlands; John F.P. Bridges, PhD, Associate Professor, Department of Health Policy and Management and International Health, John Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; Karin G. M. Groothuis-Oudshoorn, PhD, Assistant Professor, Health Technology and Services Research, University of Twente, Enschede, The Netherlands

F8: PATIENT ENGAGEMENT: WHAT IS IN A NAME?  Brown 1-2 (L2)
Presented by the Patient Engagement in Research Working Group
Moderator: Todd Berner, MD, Medical Director, Head Global Medical Affairs Strategy, Immunology, Baxalta, Inc., Bannockburn, IL, USA
Speakers: Eleanor M Perfetto, PhD, MS, Professor, Pharmaceutical Health Services Research, University of Maryland, School of Pharmacy, and Senior Vice President, Strategic Initiatives, National Health Council, Washington, MD, USA; Russell Wheeler, Patient Advocate, Leber’s Hereditary Optic Neuropathy, Winchester, UK

F9: MULTI-CRITERIA DECISION MAKING IN THE CENTRAL & EASTERN EUROPE (CEE) REGION: ARE WE THERE YET?  Space 2 (L0)
Presented by the ISPOR CEE Network
Moderator: Zoltán Kaló, PhD, Professor of Health Economics, Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary
Speakers: Vitaly Omelyanovskiy, MD, PhD, DSc, President, ISPOR Russia HTA Chapter and Director, Center for Health Technology Assessment, Russian Presidential Academy of National Economy and Public Administration, Center of Comprehensive Health Technology Assessment, Ministry of Health of the Russian Federation, Moscow, Russia; Maciej Niewada, MD, PhD, MA, CEO, HealthQuest and Professor, Department of Clinical & Experimental Pharmacology of Medical University of Warsaw, Warsaw, Poland; Rok Hren, PhD, MSc, HPH (HE), President, ISPOR Slovenia Chapter and Assistant Professor, University of Ljubljana, Ljubljana, Slovenia; Oresta Piniazhko, MSPharm, PhD student, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine

F10: MARKET ACCESS PRICING IN CENTRAL & EASTERN EUROPE (CEE): PRACTICAL GUIDE TO SUCCESSFUL REIMBURSEMENT  Space 1 (L0)
Presented by the ISPOR CEE Network
Moderator: Olha Zaliska, PhD, DSci (Pharm), President, ISPOR Ukraine Chapter and Professor, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine
Speakers: Tarik Catic, MScPharm, PhD(s), Researcher and President, ISPOR Bosnia and Herzegovina Chapter, Sarajevo, Bosnia; Yalcin Kaya, MD, PhD, Professor of Health Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary; Pavlo Matytska, PhD, Assistant Professor, Pharmacology, T. Shevchenko National University, Kyiv, Ukraine; Analin Kajtazova, PhD, Professor, Health Policy and Management, First Pavlov State Medical University of St. Petersburg, Saint Petersburg, Russia; Mariam Sorin Pavliu, PhD, MD, Associate Professor, Pharmacology, Titu Maiorescu University, Bucharest, Romania
WEDNESDAY, 11 NOVEMBER

7:30-8:30  IPSOR PERSONALIZED/PRECISION MEDICINE SPECIAL INTEREST GROUP MEETING (Open to all Attendees)  Amber 7 (L2)

All IPSOR Members interested or working in personalized, targeted, and/or precision medicine are welcome to attend the IPSOR Personalized/Precision Medicine Special Interest Group meeting. This meeting will provide an opportunity for participants to discuss the current project and identify future projects.

7:30-8:30  EDUCATIONAL SYMPOSIUM  Free and open to all delegates, no pre-registration required  Brown 3 (L2)

(Ups, see page 74 for Symposium description)

ENRICHED REAL-WORLD DATA (RWD) STUDIES: TAPPING INTO THE GROWING USE OF PATIENT LEVEL DATA TO OPTIMIZE OBSERVATIONAL STUDY DESIGN AND EXECUTION

Sponsored by IMS Health

8:45-13:45  RESEARCH POSTER PRESENTATIONS - SESSION V  South Hall (L0)

(See pages 42-43 for Research Poster Presentations Information)

8:45-9:45  WORKSHOPS - SESSION IV

(See pages 61-62 for Workshop descriptions)

USE OF REAL WORLD DATA

W18: ESTIMATION AND PREDICTION OF RELATIVE EFFECTIVENESS USING REAL-WORLD EVIDENCE: CASE STUDIES  Brown 1 (L2)

Discussion Leaders: Keith R Abrams, PhD, Professor of Medical Statistics, Department of Health Sciences, University of Leicester, Leicester, UK; Reynaldo Martina, PhD, Research Associate, Department of Health Sciences, University of Leicester, Leicester, UK; Eva-Maria Didden, PhD, Researcher, Institute of Social and Preventive Medicine, University of Bern, Bern, Switzerland; Sandro Gsteiger, PhD, HTA Statistician, MORSE - Health Technology Assessment Group, F. Hoffmann-La Roche Ltd., Basel, Switzerland

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

W20: HOW TO BRING PRO DATA INTO PAYER DECISION MAKING: PRO STRATEGIES IN PHARMACEUTICAL DEVELOPMENT  Brown 3 (L2)

Discussion Leaders: Ari Gnanasakthy, PhD, Head, Patient-Reported Outcomes, RTI Health Solutions, Research Triangle Park, NC, USA; Lynda Doward, MRes, European Head, Patient Reported Outcomes, RTI Health Solutions, Manchester, UK; Vasudha Bhal, MSc, MBA, Director, Patient Reported Outcomes, Worldwide Health Outcomes, Value & Access, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; Frank-Ulrich Fricke, PhD, Professor of Health Economics, Georg-Simon-Ohm University of Applied Science, Nurnberg, Neumarkt, Germany

CLINICAL OUTCOMES RESEARCH

W21: OPTIMISING THE CONSTRUCTION OF INDIRECT TREATMENT COMPARISONS TO REFLECT COUNTRY-SPECIFIC HTA REQUIREMENTS  Space 1 (L0)

Discussion Leaders: Craig I. Coleman, PharmD, Co-Director and Methods-Chief, University of Connecticut/Hartford Hospital Evidence-Based Practice Center, Hartford, CT, USA; Rachel Beckerman, PhD, Principal, Maple Health Group, New York, NY, USA; Marc Bardou, MD, PhD, Gastroenterologist, Centre Hospitalier Universitaire Le Bocage, Dijon, France; Mathias Flume, PhD, Head of Department, Medical Association of Westphalia-Lippe (KVWL), Dortmund, Germany

ECONOMIC OUTCOMES RESEARCH

W22: HARNESSING “BIG DATA” AND TAMING HIGH DIMENSIONAL DECISION PROBLEMS FOR ECONOMIC EVALUATION  Space 2 (L0)

Discussion Leaders: William H. Crown, PhD, Chief Scientific Officer, Optum Labs, Cambridge, MA, USA; Sarah Davis, MPhys, Senior Lecturer in Health Economics, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; Bethan Woods, MSc, Research Fellow, Centre for Health Economics, University of York, Harzington, York, UK; Miqdad Asaria, MSc, Research Fellow, Centre for Health Economics, University of York, Harzington, York, UK

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH

W23: ADDING VALUE TO EQ-5D-3L VALUATION STUDIES: TAKING STOCK / REVIEWING OPTIONS  Brown 2 (L2)

Discussion Leaders: Paul Kind, Professor, Centre for Health Economics, Management and Policy, HSE University, St Petersburg, Russia; Roisin Adams, PhD, Deputy Head, National Centre for Pharmacoconomics, Dublin, Ireland; Ling-Hsiang Chiang, PhD, Research Consultant, Phamarit Europe, Rotterdam, The Netherlands; Lucia Scalone, PharmD, PhD, Head of Outcomes Research Unit, Research Centre on Public Health (CEPS), University of Milan Bicocca, Monza, Italy

9:45-10:00  BREAK, EXHIBITS & RESEARCH POSTER PRESENTATIONS VIEWING - SESSION V  South Hall (L0)

(See pages 42-43 for Research Presentation Information)

Cookies sponsored by STAtinMED Research
HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

IP16: OUTCOME-BASED AGREEMENTS: HIGHLY USEFUL BUT TOO DIFFICULT TO IMPLEMENT – IS THAT TRUE?  Brown 1 (L2)
Moderator: Francois Lucas, PhD, Principal Consultant, Pope Woodward & Associates Ltd, St. Ives, UK
Panelists: Kathleen E. Hughes, MBA, Vice President, Health Economics and Outcomes Research, Avalere Health LLC, Washington, DC, USA; Swati Mehta, MBA, Associate Director, Pricing and Market Access, Bristol-Myers Squibb, Uxbridge, UK; Antoni Gilabert-Perramon, PhD, Managing Director of Pharmacy and Medicines, Catalan Health Service, Government of Catalonia, Barcelona, Spain

IP17: JOINT ASSESSMENTS IN EUROPE: CAN WE DO IT AND HOW?  Brown 3 (L2)
Moderator: Adrian Griffin, MSc, Vice President, HTA & Reimbursement Policy, Johnson & Johnson, Buckinghamshire, UK
Panelists: Luciana Ballini, MSc, Head of Regional Observatory for Innovation, Regional Agency for Health and Social Care – Emilia-Romagna, Bologna, Italy; Wim Goettsch, PhD, Advisor International Affairs, National Healthcare Institute (ZIN), Diemen, The Netherlands; Zoe Garrett, MIfes, Technical Adviser, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), London, UK

IP18: TO SEEK OR NOT TO SEEK PARALLEL EUROPEAN MEDICINES AGENCY (EMA)/HEALTH TECHNOLOGY ASSESSMENT (HTA) SCIENTIFIC ADVICE? THAT IS THE QUESTION  Space 1 (L0)
Moderator: Thomas J Bramley, PhD, Senior Vice President, Xcenda, Palm Harbor, FL, USA
Panelists: Ansgar Hebborn, PhD, Head, Global Market Access Policy, E Hoffmann-La Roche AG, Basel, Switzerland; Eldon Spackman, PhD, Research Fellow, Centre for Health Economics, University of York, Heslington, York, UK; Trent McLaughlin, PhD, Vice President, Xcenda, Palm Harbor, FL, USA

ECONOMIC OUTCOMES RESEARCH ISSUES

IP19: HOW DO WE EVALUATE TECHNOLOGIES WHICH ARE NOT COST-EFFECTIVE AT A ZERO PRICE?  Space 2 (L0)
Moderator: Ron Akehurst, PhD, Strategic Director, BresMed Health Solutions Ltd., Sheffield, UK
Panelists: Sarah Davis, MPhys, Senior Lecturer in Health Economics, School of Health and Related Research (SchARR), University of Sheffield, Sheffield, UK; Gavin Lewis, MSc, Head of Pricing and Market Access, Region Europe, Roche, Basel, Switzerland; Janet Robertson, BSc, BA, DipPressSci, Associate Director, Technology Appraisals, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), London, UK

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH ISSUES

IP20: PATIENT-REPORTED OUTCOMES: CAN THEIR USE IN OBSERVATIONAL (“REAL-WORLD”) RESEARCH BE CONSIDERED INTERVENTIONAL?  Brown 2 (L2)
Moderator: Matthew Reaney, CPsychol, MSc, Senior Research Scientist, ERT, Peterborough, UK
Panelists: Erin Tomaszewski, MS, Clinical Outcomes Research Scientist, Quintiles, Durham, NC, USA; Olivier Chassany, PhD, Director, Patient-Centered Outcomes Research, Paris, France

WELCOME & THIRD PLENARY SESSION  Gold (L2)

WELCOME
(See page 86 for Biographical Information)
Daniel Malone, PhD, RPh, 2015-2016 ISPOR President, Professor of Pharmacy, College of Pharmacy and Associate Professor, Mel & Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA

THIRD PLENARY SESSION: RECOMMENDATIONS FROM THE ISPOR MULTI-CRITERIA DECISION ANALYSIS EMERGING GOOD PRACTICE TASK FORCE AND REMAINING CONTROVERSIES
(See pages 86-89 for Biographical Information)
Multi-criteria decision analysis (MCDA) is an emerging new practice using a broad set of methodological approaches to assist in decision making, especially in an era of expensive but valuable technologies trading multiple criteria. The ISPOR MCDA Task Force Report discusses different approaches for conducting MCDA. Panelists will present emerging good practice recommendations presented in the Task Force report and identify remaining areas of controversy.

Moderator: Daniel Malone, PhD, RPh, Professor of Pharmacy, College of Pharmacy and Associate Professor, Mel & Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA

PRESENTATION OF THE TASK FORCE REPORTS: EMERGING GOOD PRACTICES FOR CONDUCTING MCDA

Speakers:
Maarten J. IJzerman, PhD, Professor of Clinical Epidemiology & HTA & Vice Dean, Health & Biomedical Technology, Faculty of Science & Technology, University of Twente, Enschede, The Netherlands
Kevin Marsh, PhD, Senior Research Scientist & EU Director of Modelling and Simulation, Evidera, London, UK

IDENTIFICATION OF REMAINING CONTROVERSIES AND SOLUTIONS FOR USING MCDA IN HEALTH CARE

Speakers:
A. Brett Hauber, PhD, Senior Economist & Vice President, Health Preference Assessment, RTI Health Solutions, Research Triangle Park, NC, USA
Mónica Duarte Oliveira, PhD, MSc, Associate Professor, Department of Engineering and Management, Instituto Superior Técnico, University of Lisbon, Lisbon, Portugal

TASK FORCE RESPONSE & DISCUSSION

Speakers:
Nancy Devlin, PhD, Director of Research, Office of Health Economics, London, UK
Praveen Thokala, MASc, PhD, Research Fellow, University of Sheffield, Sheffield, UK
ISPOR 18th Annual European Congress
7-11 November 2015 | MiCo – Milano Congressi | Milan, Italy

PROGRAM & SCHEDULE OF EVENTS CONTINUED: WEDNESDAY, 11 NOVEMBER

12:30-12:45  ISPOR 18th ANNUAL EUROPEAN CONGRESS RESEARCH PRESENTATION AWARDS  Gold (L2)
Moderator: Daniel Malone, PhD, RPh, 2015-2016 ISPOR President, Professor of Pharmacy, College of Pharmacy, and Associate Professor, Mel & Enid Zuckerman College of Public Health, University of Arizona, Tucson, AZ, USA

ISPOR BEST PODIUM PRESENTATIONS
Presented by: Anthony J Hatswell, MSc, Co-Chair, 18th Annual European Congress Research Review Committee, Principal Consultant (HTA Methodology), BresMed and Department of Statistical Science, University College London, Sheffield, UK

ISPOR BEST POSTER PRESENTATIONS
Presented by: Paolo Angelo Cortesi, PhD, Chair, ISPOR 18th Annual European Congress Research Review Committee and Researcher, Research Centre on Public Health (CESP), University of Milano – Bicocca, Monza, Italy

12:45-13:45  LUNCH, EXHIBITS & RESEARCH POSTER PRESENTATIONS VIEWING - SESSION V South Hall (L0)
(See pages 42-43 for Research Poster Presentations Information)

12:45-13:45  POSTER AUTHOR DISCUSSION HOUR - SESSION V South Hall (L0)
(See pages 42-43 for Research Poster Presentations Information)

13:45-14:45  WORKSHOPS - SESSION V
(See pages 62-63 for Workshop descriptions)

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

W24: ARE ANTIMICROBIALS PAVING THE WAY FOR ALL PHARMACEUTICALS? – A WORKSHOP ON THE COMMERCIAL SUSTAINABILITY OF R&D Brown 3 (L2)
Discussion Leaders: Alistair Mcguire, PhD, Professor of Health Economics, London School of Economics, London, UK, Michael Drummond, MCom, DPhil, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; Monique Martin, PharmD, MSc, MBA, Vice President & General Manager HEOR Europe, MAPI, Uxbridge, UK

W25: INCORPORATING EQUITY INTO HEALTH TECHNOLOGY ASSESSMENT: AN ILLUSTRATION AND CRITICAL REVIEW OF GOOD PRACTICE Space 1 (L0)
Discussion Leaders: Kevin Marsh, PhD, Senior Research Scientist & EU Director of Modelling and Simulation, Evidera, London, UK; Vitaly V. Omelyanovskiy, MD, PhD, Director, Center of HTA, Moscow, Russia; Alec Morton, PhD, Professor, Management Science, University of Strathclyde, Glasgow, UK; Sumitra Sri Bhashyam, PhD, Research Associate III, Modelling and Simulation, Evidera, London, UK

USE OF REAL WORLD DATA

W26: MAXIMIZING VALUE: REALIZING THE POTENTIAL OF ROUTINELY COLLECTED DATA Space 2 (L0)
Discussion Leaders: Heiner C. Bucher, MD, MPH, Professor, Department of Clinical Research, Basel Institute for Clinical Epidemiology & Biostatistics, Basel, Switzerland; Ed Mills, PhD, MSc, Director, Redwood Outcomes, Vancouver, BC, Canada; Christopher O'Regan, MSc, Head of Health Technology Assessment & Outcomes, Merck Sharp & Dohme Limited, Hertfordshire, UK

ECONOMIC OUTCOMES RESEARCH

W27: ASSESSING THE SOCIETAL, HEALTH CARE, AND PATIENT IMPACT OF LARGE HEALTH CARE INNOVATION PARTNERSHIPS USING HEALTH ECONOMIC MODELING METHODS: LESSONS FROM THE EUROPEAN INNOVATION PARTNERSHIP ON ACTIVE AND HEALTHY AGEING (EIP ON AHA) Brown 2 (L2)
Discussion Leaders: Christian Erst Heinrich Boehler, PhD, MSc, Scientific Officer, Joint Research Centre (JRC), Institute for Prospective Technological Studies (IPTS), European Commission, Seville, Spain; Lotte Steuten, PhD, Associate Professor, Fred Hutchinson Cancer Research Center, University of Washington and Chief Executive Officer, Panaxea by, Seattle, WA, USA; Leandro Pecchia, PhD, MSc, Assistant Professor, School of Engineering, University of Warwick, Coventry, UK; Miriam Vollenbroek, PhD, Professor, Faculty of Electrical Engineering, Mathematics and Computer Science, University of Twente and Roessingh Research and Development (RRD), Enschede, The Netherlands

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH

W28: SECONDARY ANALYSIS OF QUALITATIVE DATA TO INFORM THE DEVELOPMENT OF PRO INSTRUMENTS Brown 1 (L2)
Discussion Leaders: Monica Hadi, PhD, Research Manager, Patient-Centered Outcomes, Mapi Group, London, UK; Paul Swinburn, MRes, Research Director, Patient-Centered Outcomes, Mapi Group, London, UK; Elizabeth Gibbons, MSc, Senior Research Scientist, Health Services Research Unit, University of Oxford, Oxford, UK

14:45-15:00  BREAK South Hall (L0)
Cookies sponsored by STATinMED Research
15:00-16:00  WORKSHOPS - SESSION VI

### HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

**W29: HOW SHOULD WE BE RESPONDING TO CONDITIONAL APPROVALS FROM HTA BODIES?**  *Brown 3 (L2)*

**Discussion Leaders:** Mondher Toumi, MD, MSc, PhD, Professor of Public Health, Department of Public Health, Aix-Marseille University, Marseilles, France; Alan A. Martin, MSc, Director, Value Evidence Analytics, Research and Development, GlaxoSmithKline, Uxbridge, UK; Yumi Asukai, MSc, Director Value Evidence Analytics, Research and Development, GlaxoSmithKline, Uxbridge, UK

### USE OF REAL WORLD DATA

**W30: MANAGING THE EFFECTS OF CHANNELING IN RELATIVE EFFECTIVENESS STUDIES OF NEWLY LAUNCHED MEDICATIONS**  *Space 1 (L0)*

**Discussion Leaders:** Jessica Jalbert, PhD, Director of Pharmacoepidemiology, LASER Analytica, New York, NY, USA; Christiane Gasse, PhD, Senior Researcher, Aarhus Universitet, Aarhus, Denmark; Tjeerd Van Staa, MD, PhD, Professor of Health Research, Farr Institute of Health Informatics Research, University of Manchester, Manchester, UK; Billy Amzal, PhD, Global Scientific Vice President, LASER Analytica, London, UK

### CLINICAL OUTCOMES RESEARCH

**W31: NETWORK META ANALYSIS MODELS FOR DOSE-RESPONSE AND CLASS EFFECTS IN DECISION MAKING**  *Brown 2 (L2)*

**Discussion Leaders:** Rhiannon Kate Owen, MSc, Research Associate/NIHR Doctoral Research Fellow, Department of Health Sciences, University of Leicester, Leicester, UK; Kristian Thorlund, PhD, MStat, Director, Redwood Outcomes, Vancouver, BC, Canada; David Mawdsley, PhD, Research Associate, School of Social and Community Medicine, University of Bristol, Bristol, UK; Timothy Reason, MSc, Senior Consultant, Real-World Evidence Solutions, IMS Health, London, UK

### ECONOMIC OUTCOMES RESEARCH

**W32: HOW TO COMBINE OPEN ACCESS ARTICLES AND OPEN ACCESS ECONOMIC EVALUATION MODELS IN HEALTH CARE PROGRAMMES: REAL TIME UPDATING AND LOCAL CUSTOMIZATION OF PUBLISHED ECONOMIC MODELS**  *Space 2 (L0)*

**Discussion Leaders:** Giorgio L. Colombo, MSc, Research Associate/NIHR Doctoral Research Fellow, Department of Health Sciences, University of Pavia, Milan, Italy; Sandra Le, PhD, Editorial Development Manager, Dove Medical Press Limited, Macclesfield, UK; Stefano Govoni, Pharmacologist & Professor Department of Drug Sciences, School of Pharmacy, University of Pavia, Milan, Italy; Laura Caresia, MD, Medical Director, McCann Complete Medical, Milan, Italy

**W33: UNCERTAINTY OF UNCERTAINTY ESTIMATES IN ECONOMIC MODELLING OF ONCOLOGY**  *Brown 1 (L2)*

**Discussion Leaders:** T Lanitis, MSc, Senior Research Associate, Evidera, London, UK; Zoltán Kaló, PhD, Professor of Health Economics, Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary; Noemi Muszbek, MSc, Senior Research Scientist, Evidera, London, UK

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- Each poster presentation has been assigned a specific numbered board location, which is shown next to the poster presentation title. Please note this is different than the poster code (e.g. PHP1, PCV57), which was assigned to each poster presentation upon acceptance.
- Poster presentation titles and authors, as well as the numbered board location and abstract page reference in Value in Health, are available on the myISPORMilan.zerista.com meeting platform and mobile app. This information is also available as a PDF on the ISPOR website and as a handout at the Poster Help Desk (please note quantities are limited).
- An Author index is available in Value in Health 18 (7), which is available near ISPOR registration and online at http://www.ispor.org/valueinhealth_index.asp.
- Poster board numbering is available on the floor plan on page 43 and row locations (by topic) are available in the table below.

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Monday, 9 November & Tuesday, 10 November

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Saturday 7 November 2015
18:30 – 19:30
Brown 3 (L2), MiCo - Milano Congressi
Milan, Italy

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HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

IP1: WHAT IS THE ROLE OF ECONOMIC EVALUATION IN PRICING AND REIMBURSEMENT OF MEDICINES? A COMPARISON BETWEEN ENGLAND, GERMANY, AND FRANCE

Gold (L2)
Moderator: Wim Goettsch, PhD, Advisor International Affairs, National Healthcare Institute (ZIN), Diemen, The Netherlands
Panelists: Meindert Boysten, PharmD, MSc, Programme Director, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK; Andreas Gerber-Grote, MD, PhD, Head of Health Economics, Institute for Quality and Efficiency in Healthcare (IQWiG), Cologne, Germany; Jean-Luc Harousseau, MD, PhD, President, French National Authority for Health (HAS), Saint-Denis La Plaine, France
ISSUE: European governments are increasingly using economic evaluations as an aide to make decisions about reimbursement of medicines by national health insurance schemes. But it is not clear how economic evaluations of medicines are used in reimbursement and price negotiation. The most comprehensive use of economics has been in England where economic evaluation is fully integrated in National Institute for Health and Care Excellence (NICE) appraisals and is guided by the existence of a cost-effectiveness threshold. In Germany, economic evaluation plays a somewhat minor role in the process of early benefit assessment that was established in January 2011. In France, since October 2013, the appraisal of medicines by HAS must include an economic evaluation for innovative products, which should assist the government in price negotiation. These different approaches raise questions about their impact on the outcome and timeliness of reimbursement decisions and pricing.

OVERVIEW: The panelists will present and discuss the pros and cons of the different perspectives on economic evaluation. Meindert Boysten will analyze the impact of NICE economic evaluations on public decisions, focusing on some examples. He will present the discussions around value-based pricing. Andreas Gerber-Grote will focus on the process and outline the relevance of data on the size of the target population and subpopulations, as well as on cost of the medicine under evaluation and its comparator(s). He will present how different stakeholders perceive the strengths and limitations of the process after 4 years of early benefit assessment. Jean-Luc Harousseau will present an analysis of the first economic evaluations since October 2013, their use by the government pricing committee in the process of price negotiation, and the current discussions of the role of cost-effectiveness as well as budget impact analysis of medicines in France. The panelists will compare, through examples, how economic evaluation has impacted reimbursement decisions and pricing in their respective countries.

IP2: POSSIBLE INCREASED SYNERGY BETWEEN HEALTH TECHNOLOGY ASSESSMENT (HTA) AND REGULATORY AGENCIES: OPPORTUNITY OR CHALLENGE FOR MEDICAL DEVICES?

Brown 1-2 (L2)
Moderator: Christopher Henshall, PhD, Associate Professor, Health Economics Research, Brunel University, London, UK
Panelists: Les Levin, MA, MD, Founding Chief Scientific Officer, MaRS EXCITE, Toronto, ON, Canada; Francois Meyer, MD, Advisor to the President, International Affairs, French National Authority for Health (HAS), Paris, France; Pascale Brasseur, EconD, Chair, HTA Working Group, Eucomed, Brussels, Belgium
ISSUE: Regulatory approval and reimbursement are necessary to bring health technologies to market: both are distinct processes and HTA has historically been focused on effectiveness and economic analysis. In its Strategy Paper (October 29, 2014), the European HTA Network indicates that for medical devices, synergies should be explored in relation to: Assisting medical device conformity assessments (incl. development of guidance for clinical evaluation of specific types of medical devices) Conducting early dialogues/scientific advice with developers of technologies (pre-market access) Designing studies that could meet requirements for post market clinical follow-up HTA on medical devices is however performed in a sporadic manner and in general there is disconnect between HTA and reimbursement. It is therefore not clear whether parallel evaluation models could help achieve quicker patient access.

OVERVIEW: Synergistic approach with streamlining of regulatory and reimbursement processes and aligning of evidence requirements may carry positive implications in terms of patient care, innovation and system sustainability. They may also carry risks; harmonization may lead to over-regulation, hindering the abilities for the markets to function and translating into patient access failures. Currently, data collection for drugs predominantly occurs at the pre-market phase, whereas for devices, it is focused on post-market surveillance. Greater progress has been noted with achieving consensus on drug review methodology between agencies whereas, it remains less resolved with medical devices. Harmonization initiatives include, for instance, the Federal Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS)’ memorandum of understanding for parallel review, the Health Canada and CADTH’s information-sharing agreement, or the MaRS EXCITE and EXCITE International programs. Panelists will express their views on the barriers and facilitators of these initiatives: Les Levin will present on EXCITE International. Francois Meyer will provide information on early dialogue with device Manufacturers in the frame of EUvHTA IA2 and SEED. The third panelist will present the industry point of view. The audience will be invited to participate in the discussion on what would work and what would not work.

IP3: SPEED OR LESS UNCERTAINTY? TRADE-OFFS IN ADAPTIVE PATHWAY IMPLEMENTATION AND POTENTIAL PRICING AND REIMBURSEMENT RESPONSES

Brown 3 (L2)
Moderator: Susanne Michel, MD, European Practice Lead, Evidera, London, UK
Panelists: Yvonne-Beatrice Booher, MD, MBA, Professor for Pharmamanagement, Faculty of Applied Natural Sciences, Cologne University of Applied Sciences, Leverkusen, Germany; Martin Buxton, BA, Emeritus Professor, Health Economics Research Group (HERG), Brunel University, Uxbridge, UK; J Jaime Caro, MDCM, Chief Scientist, Evidera, Lexington, MA, USA
ISSUE: Adaptive Pathways (AP) aim to provide more rapid access to medicines and allow better targeted allocation of scarce health care resources. The process may entail a stepped development of evidence substantiating the value of a new treatment. One of the ideas is to explore new avenues for evidence generation, in addition to the traditional randomized clinical trial. Incremental development of value substantiation implies accumulating evidence over time, while requiring critical value assessment, pricing and reimbursement decisions at milestones. Therefore, decision-making needs to account for a higher level of uncertainty, especially at the initial milestones. Uncertainty may result from more limited data regarding efficacy, effectiveness and safety, as well as HRQoL and health economic values. Trade-offs between speed of getting treatments to patients and the degree and nature of uncertainty have to be addressed for sound pricing and reimbursement decisions to become possible in an AP framework.

OVERVIEW: Although AP has been discussed by researchers involved in NEWSDIG and CASMI, little coverage has been devoted to how decision-making will deal with larger uncertainty in the evidence. Yvonne-Beatrice Bühler will discuss the payer’s perspective, namely what is needed to justify reimbursement from national public pharmaceutical budgets and how price-setting may be changing in an AP environment using the current German context. Martin Buxton will discuss the potential opportunity costs of reimbursing technologies with high uncertainty, and of investing health-system time/effort to attempt to reduce future uncertainty. Jaime Caro will discuss new evidence generation concepts such as BASE trials and adjustments in reimbursement and pricing decision making. The issue panel should allow participants to formulate an action plan addressing adjustments in their value creation and assessment process. The moderator will summarize and contrast success factors with the challenges involved, from the EU markets’ perspective and invite the audience to contribute and share thoughts/experiences.
APPLY PROCESSES ESTABLISHED FOR DRUGS OR DO WE NEED TO PURSUE IP6: ASSESSMENT OF THE VALUE OF MEDICAL DEVICES: CAN WE SIMPLY ISSUES
HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES
HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

ISSUE PANELS – SESSION II: TUESDAY, 10 NOVEMBER: 13:45-14:45

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES
IP6: ASSESSMENT OF THE VALUE OF MEDICAL DEVICES: CAN WE SIMPLY APPLY PROCESSES ESTABLISHED FOR DRUGS OR DO WE NEED TO PURSUE SEPARATE PROCESSES FOR DEVICES?
Brown 1-2 (L2)
Moderator: Wolfgang Greiner, PhD, Head, Department for Health Economics and Health Care Management, School of Public Health, Bielefeld University, Bielefeld, Germany
Panelists: Thomas Mittendorf, PhD, Managing Director & Vice President, Xcenda GmbH, Hannover, Germany; Ron Akehurst, PhD, Strategic Director, BresMed Health Solutions Ltd, Sheffield, UK; Alric Ruether, MD, PhD, Head, Department of Health Care Quality, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany
ISSUE: Health Technology Assessment (HTA) bodies have established processes for many types of medical interventions. However, many of the processes were developed to be applied to drugs with limited focus on medical devices. The panel will explore whether the processes established for medications are suitable for devices or whether alternative routes of assessment need to be discussed.

ISSUE PANELS – SESSION I: MONDAY, 9 NOVEMBER: 11:15-12:15 CONTINUED

ECONOMIC OUTCOMES RESEARCH ISSUES
IP4: MANAGEMENT OF SPECIALTY DRUGS IN THE UNITED STATES AND EUROPE: ARE WE BALANCING INNOVATION AND AFFORDABILITY?
Space 2 (L0)
Moderator: John E. Schneider, PhD, Chief Executive Officer, Avalon Health Economics, Morristown, NJ, USA
Panelists: James Robinson, PhD, Professor, Public Health, University of California, Berkeley, Berkeley, CA, USA; Ansgar Hebborn, PhD, Head - Global HTA & Payment Policy, Global Pricing & Market Access, F. Hoffmann-La Roche AG, Basel, Switzerland
ISSUE: All health systems seek to promote development of pharmaceutical innovation, on the one hand, and the affordability of drugs and other components of care, on the other. The United States and the European Union have pursued quite different approaches to this common goal of innovation and affordability, but it is unclear which approach is better. The US maintains a diversified and fragmented HTA approach, given its mix of public and private insurers who are prohibited from coordinating their initiatives, while the EU pursues a more unified and standardized HTA and pricing strategy. At the provider level, the US is promoting integrated physician and hospital organizations, paid increasingly on a capitation basis, whereas many European nations maintain a more traditional separation between physician practices and hospital organizations. The US and EU approaches are converging in some respects and maintaining their differences in other respects. On the surface, it seems that the US approach fosters greater innovation in drugs, devices, and mobile technologies, while the European approach fosters greater affordability and equitable access to care. The deeper impact of each system is open for debate.
OVERVIEW: This panel will compare and assess the approaches adopted by the health systems (including insurers and providers) in the US and the EU with respect to the coverage, pricing, utilization management, and patient engagement for specialty drugs. Examples will include drugs for cancer and hepatitis C. While acknowledging the contributions of the alternative approaches, each of the panelists will highlight the advantages of one system (Robinson for the US, Hebborn for the EU) so as to stimulate discussion. The session will be highly interactive, with audience participation encouraged by the moderator.

IP5: BLOG IT, TWEET IT, LIKE IT, OR BIN IT? THE ROLE OF SOCIAL MEDIA RESEARCH ISSUES
Space 1 (L0)
Moderator: Louise Humphrey, MSc, Director, Abacus International, Manchester, UK
Panelists: Raj Mahaputra, LLB (Hons), Chair, National Ankylosing Spondylitis Society, London, UK; Diana Rofail, PhD, CPsychol, Global Head of Patient-Centered Outcomes Research, Neuroscience and Metabolism, Roche Products Limited, Welwyn Garden City, UK; Thomas G Willgoss, PhD, Project Lead, Clinical Outcomes Assessment, Abacus International, Manchester, UK
ISSUE: Use of social media data (SMD) in patient-reported outcome (PRO) research is a hot topic but, to date, discussion has been conceptual at best. Furthermore, there is little guidance as to how SMD should be utilised in this context. This issue panel will focus on three critical questions: 1) WHAT (definitions), 2) WHY (benefits/challenges), 3) HOW (methodologies). WHAT: Louise Humphrey will introduce discussion and present a framework for defining SMD and suitability of SMD types for PRO research. SMD encompasses diverse platforms (e.g. Twitter to blogging), thus establishing a common framework is critical to the discussion. WHY: Different perspectives on SMD’s benefits and challenges will then be presented. Raj Mahaputra will share his and other’s positive experiences of using social media as a patient and patient advocate. Tom Willgoss will then present challenges associated with SMD for instrument development based on pertinent case studies. Lastly, Diana Rofail will discuss the opportunities (e.g. the ability to capture difficult-to-reach populations) and potential barriers (e.g. issues relating to diagnosis verification) for SMD from an industry perspective. HOW: Building on the case study examples, Tom Willgoss will showcase a methodology to identify, capture and analyse SMD which harnesses its benefits whilst addressing key challenges, as raised by the panel. Finally, Louise Humphrey will encourage the audience to ask questions and provide their perspectives.
OVERVIEW: SMD is gaining recognition as a valuable source of patient-derived data in a time when patient-led drug development is a major focus of the pharmaceutical industry. Despite this, the diversity of platforms encompassed by ‘social media’ has led to confusion as to which are most important for PRO research. Furthermore methodological guidance is lacking. This panel discussion will establish a framework for a more transparent, robust approach for optimising SMD, incorporating the patient, industry and instrument developer perspectives.

OVERVIEW: Due to the relative limited impact of medical devices, most HTA bodies have focused in the past on the evaluation of drugs. As such, HTA methods have predominantly evolved more effectively to assess the value of drugs, with little attention paid to methods and processes appropriate for medical devices. Because of different regulatory pathways for devices, the existing level of evidence available for medical devices in many cases differs from that of medications as does the product life cycle and physician adoption curve. The panel will give the audience a basic understanding of differences between drug and medical devices assessments in different markets and debate the case for similar or different processes than for drugs. Dr. Mittendorf will give an overview on the challenges, providing a methodological framework. Dr. Ruether will set out the German position with its prime focus on clinical, patient-relevant benefit and proof via high-standard unbiased clinical research. Dr. Akehurst will focus on the UK, which focuses not only on clinical benefits but also economic implications. Dr. Greiner will guide discussions with a question and answer session and conclude by summarizing key messages on challenges and opportunities ahead.
ISSUE PANELS - SESSION II: TUESDAY, 10 NOVEMBER: 13:45-14:45 CONTINUED

IP7: ARE CURRENT ICER THRESHOLDS OUTDATED? DOES MCCA OFFER A MORE HOLISTIC APPROACH TO ASSESSING THE VALUE OF INNOVATIVE TECHNOLOGIES?

Space 1 (L0)
Moderator: Zeba M. Khan, RPh, PhD, Vice President, Celgene Corporation, Summit, NJ, USA
Panelists: John Proach, MBA, Executive Vice President, Pricing and Market Access, Market Access Solutions LLC, Raritan, NJ, USA; Andrew Briggs, DPhil, MSc, William R. Lindsay Professor of Health Economics, Department of Health Economics & Health Technology Assessment, Institute of Health & Wellbeing, University of Glasgow, Glasgow, UK; Maarten J. Izerman, PhD, Professor of Clinical Epidemiology & HTA & Vice Dean, Health & Biomedical Technology, Faculty of Science & Technology, University of Twente, Enschede, The Netherlands

ISSUE: In countries that use cost-effectiveness as the methodology driving reimbursement decisions, an implicit or explicit incremental cost-effectiveness ratio (ICER) threshold is typically used as a benchmark for coverage/funding decisions for new healthcare technologies. Australia, Canada and New Zealand utilize implicit threshold values derived from previous resource allocation decisions; Australia uses AUS$69,900/QALY, Canada accepts up to CANS80,000/QALY and New Zealand uses NZ$20,000/QALY. Additionally, the UK established an ICER threshold of £20,000 – £30,000/QALY in 1999. The rationale for the use of ICER thresholds in evaluating the value of new innovative technologies is well-established; however, several thought leaders have published their concerns on the rigidity and out-of-date ICER thresholds used and their inability to account for value-based attributes. Conversely, the concept of multi-criteria decision analysis (MCDA) is gaining increasing acceptance as a robust approach to holistic value assessment for reimbursement decisions due to its potential to consider any criteria that the decision-maker judges relevant as well as the level of preference assigned to each included criteria. The potential use of MCDA in HTAs is being investigated in Canada, Germany, UK, Switzerland, South Africa and Thailand. Should the current ICER threshold approach incorporate an algorithm that captures the importance of a therapy’s attributes that effectively address the degree of disease severity and unmet needs?

OVERVIEW: During the discussion moderated by Zeba M. Khan, experts will contribute distinct perspectives related to the issue of evaluating innovative healthcare technologies: 1) Findings from a survey of ISPOR 2014 Amsterdam attendees outlining different stakeholder perspectives on ICER thresholds; 2) The ICER-threshold based approach and 3) The perspective on MCDA methodology, expressed as the weighted average of preferences and performance scoring. Panelists will then discuss contrasting experiences with the utilization of both methods in assessing the value of therapeutic innovation and field audience questions for 20 minutes.

IP8: THE COST OF NO EUROPE: ARE THERE COSTS AND CONSEQUENCES OF LOCALIZED OR CENTRALIZED ASSESSMENT OF RELATIVE EFFICACY?

Space 2 (L0)
Moderator: Alastair Kent, OBE, Director, Genetic Alliance UK, London, UK
Panelists: Andrea Rappagliosi, LLM, Vice President, Market Access, Health Policy and Medical Affairs, Sanofi Pasteur MSD, Lyon, France; Carole Longson, PhD, Director, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), Manchester, UK; Jacco Keja, PhD, Senior Principal, Real-World Evidence Solutions & HEOR, IMS Health, London, UK and Lecturer, RWES, IMS Health, Rotterdam, The Netherlands

ISSUE: Despite attempts to harmonize access to medicines for patients in Europe, heterogeneity in the way national HTA agencies interpret the clinical data is causing increasing divergence and unpredictability in how medicines are evaluated and when (or if) they become available to patients. Analysis of HTA decisions over the last five years showed greatest alignment in local recommendations for therapeutic areas that have well-accepted benchmarks, guidelines, and clear subpopulations. Assessments were least aligned for therapeutic areas where there is room for interpretation on the level of improvement, outcome measure chosen, and applicability of the evidence. The heterogeneity and inconsistency of decisions raises the question as to where convergence efforts should be focused, and how much individualism should HTA agencies be willing to relinquish for the collective benefit?

OVERVIEW: Continued inconsistent standards and results of relative efficacy assessments (REA) across Europe create complications and adverse consequences for pharmaceutical manufacturers as well as health systems. A review of recent HTA decisions reveals varying degrees of divergence among countries, driven by the nature of the therapeutic area, the critical endpoint, and trial design. The panel will debate the implications of a more coordinated European approach, which can lead to the production of REAs and the adoption of more consistent methodological standards, while maintaining Member State’s autonomy to determine the value of medicines in their specific setting. Different points of view will be taken on how much individualism should HTA agencies be willing to trade for a European system of REA given the agreed goals of earlier and more equitable patient access across Europe. Jacco Keja will present a review of recent HTA decisions, Andrea Rappagliosi will outline the industry views on what elements can be shared across markets, and Carole Longson will adopt the individual Member State perspective on collaboration and national autonomy.

CLINICAL OUTCOMES RESEARCH ISSUES

IP9: IS A SINGLE EVIDENCE BASE POSSIBLE ACROSS EUROPE? HOW SHOULD EVIDENCE GENERATION EFFORTS BE FOCUSED TO MEET PAYER REQUIREMENTS FOR MARKET ACCESS?

Space 2 (L0)
Moderator: Ad Rietveld, MD, MBA, Director, RIW & Partners, Royston, UK
Panelists: Wil Toenders, MSc, Consultant, ToendersdeGroot, Utrecht, The Netherlands; Bernard Avouac, MD, Former President, Transparency Commission, Paris, France; Wolfgang Kaesbach, PhD, Former Head, National Association of Statutory Health Insurance Funds (GKV), Berlin, Germany

ISSUE: As health care budgets across Europe are becoming increasingly strained, payers are becoming ever more focused on the clinical value of products in relation to the price requested. The key issue is that although European evidence requirements for regulatory approval are relatively clear, the data requirements and methodology applied by payer organisations across Europe can be diverse. A key challenge is how to focus efforts to create an evidence package for new pharmaceutical products to optimise market access across Europe and satisfy payer bodies in an era of increasing scrutiny about the clinical and economic contribution. Using concrete product examples, we will present research on the divergence of payer decisions between countries and the supporting evidence packages.

OVERVIEW: The different evidence required by payer bodies for successful reimbursement across Europe can cause significant challenges from a clinical development perspective. However, despite the differences between markets, there are common issues and perspectives payers take towards evidence packages for new products. Wolfgang Kaesbach will utilise his experience of the German healthcare market and the evidence requirements for the AMNOG process. Wil Toenders will provide a perspective from the Netherlands and the data packages which are necessary to secure reimbursement via the ZIN. Bernard Avouac will outline how the Transparency Commission review clinical evidence and what is needed to provide favourable reimbursement in France. All participants will utilise examples from their markets to enrich the discussion and provide an outlook for the future.

ECONOMIC OUTCOMES RESEARCH ISSUES

IP10: QUALITY-ADJUSTED LIFE YEARS (QALYS) – HELP OR HINDRANCE IN SUPPORTING HEALTH CARE DECISION MAKING?

Brown 3 (L2)
Moderator: Emelie Maria Heintz, PhD, Health Economist, Swedish Council on Health Technology Assessment (SBU), Stockholm, Sweden
Panelists: Mark J. Sculpher, MSc, PhD, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; Ariel Beresniak, MD, MPH, PhD, Chief Executive Officer, Data Mining International, Geneva, Switzerland; Irina Cleemput, PhD, MSc, Senior Health Economist, Belgian Health Care Knowledge Institute (KCE), Brussels, Belgium

ISSUE: This issues panel session will present a scientific debate about the advantages and disadvantages of using quality-adjusted life years (QALYS) as outcome measure for health economic evaluations. The panelists represent
different scientific perspectives and standpoints concerning the acceptability of QALY’s. Mark Sculpher will represent the academic perspective from the UK where QALY’s have been the outcome measure since the foundation of NICE. For the ECHOUTCOME project, Ariel Beresniak will take a critical stance on the QALY. As a third speaker from a HTA agency, Irina Cleemput will represent the governmental perspective on the use of QALY’s for decision-making.

OVERVIEW: In May 2015, EUnetHTA published an overview and guideline on methods for health economic evaluations. The overview covered existing methodological guidelines in the 33 countries with organizations involved in EUnetHTA. The identified commonalities between the guidelines were used to formulate recommendations on a European level. However, there are several issues on which the guidelines vary in their recommendations. One such issue concerns QALYs as the main outcome measure in cost-effectiveness analyses. The majority of the guidelines specify that the preferred outcome measure is QALYs, or both QALYs and life years gained, but some guidelines do not recommend QALYs at all, only in special circumstances or only in complementary analyses. The QALY has been criticized from a methodological as well as an ethical perspective. However, it is often argued to be good enough and the best measure we have since there is no good alternative. Culturally and ethically held beliefs in the different countries have made this question a quite controversial issue. In this panel we will bring together views from countries that have a long experience in using QALYs in health economic analyses as well as from countries that have not yet fully established health economics in their decision-making.

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

IP11: BUILDING LIGHT HTA APPROACH IN CENTRAL AND EASTERN EUROPEAN COUNTRIES BASED ON HTA RECOMMENDATIONS IN WESTERN EUROPEAN COUNTRIES: MORE HARM THAN GOOD?

Gold (L2)

Moderator: Finn Berlum Kristensen, MD, PhD, Professor, Health Services Research & Health Technology Assessment, University of Southern Denmark and Director, EUnetHTA Secretariat, Danish Health and Medicines Authority, Copenhagen, Denmark

Panelists: Katarzyna Kolasa, PhD, Market Access Director, Oy H. Lundbeck Ab, Turku, Finland; Mirjana Huic, MD, PhD, Assistant Director, Department for Development, Research and Health Technology Assessment, Agency for Quality and Accreditation in Health Care and Social Welfare, Zagreb, Croatia; Zoltán Kaló, PhD, Professor of Health Economics, Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary

ISSUE: The opportunity cost of inappropriate health policy decisions is greater in Central and Eastern European (CEE) compared to Western European (WE) countries because of poorer population health and more limited health care resources. Application of health technology assessment (HTA) prior to health care financing decisions can improve the allocative efficiency of scarce resources. However, few CEE countries have sufficient human and financial resources for HTA implementation.

OVERVIEW: Some stakeholders propose that light HTA system with a scorecard based on HTA recommendations of established HTA agencies (e.g. in UK, Germany, France) can improve the evidence base of reimbursement decisions in CEE countries without duplication of efforts, and eventually improve patient access to high-cost technologies. Such a system was implemented in Romania, and considered in several other CEE countries. Other stakeholders argue that such scorecards cannot increase the evidence base of decisions, as transferability of HTA recommendations from WE to CEE is limited without including local adaptation of the most critical HTA elements and understanding non-transparent pricing agreements. In addition such light HTA approach would create disincentives to investment into HTA in CEE, which can be detrimental for these countries due to decreased retention of CEE HTA experts in their own countries and limited interest in HTA capacity building. Increasing relative importance of recommendations of WE HTA agencies might even allow them to achieve higher confidential price discounts, which eventually could result in lower prices in WE than in CEE. Panelists will present their experiences and perspectives related to this light HTA approach from different viewpoints (academic, HTA agency and industry view), and discuss how international collaboration in HTA implementation can be improved in CEE countries.

IP12: WHAT ARE THE OPPORTUNITIES AND CHALLENGES IN DEVELOPING TRANSPARENCY OF CLINICAL (TRIAL) DATA?

Brown 1-2 (L2)

Moderator: Meindert Boysen, PharmD, MSc, Programme Director, Centre for Health Technology Evaluation, National Institute for Health and Clinical Excellence (NICE), Manchester, UK

Panelists: Noel Wathion, PharmD, Chief Policy Adviser, European Medicines Agency (EMA), London, UK; Richard Bergstrom, PharmD, Director General, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium; Beate Wieseler, PhD, Head of Drug Assessment, Institute for Quality and Efficiency in Health Care (IQWiG), Cologne, Germany

ISSUE: Although the debate around transparency of clinical (trial) data has been intensive and sometimes adversarial over the past years, it has also resulted in significant policy developments, especially in the context of regulation of medicinal products in Europe. The implications for health technology assessment (HTA) have been less well rehearsed. Representatives from regulators, HTA agencies and pharmaceutical industry will debate the advantages and disadvantages of clinical (trial) data transparency in the context of supporting earlier access to medicines.

OVERVIEW: The European Medicines Agency (EMA) published its policy on publication of clinical data for medicinal products for human use in October 2014. In the first phase, effective from January 2015, clinical (study) reports will be made available when the medicinal product receives its marketing authorisation; ‘view-on-screen-only’ for any user, and ‘downloadable’ for identified users. Individual pharmaceutical companies have at the same time made arrangements for sharing of clinical trial data with interested parties, while the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) launched their joint ‘principles for responsible clinical trial data sharing’. 2016 will bring the new Clinical Trials Regulation, a portal and a database housing extensive details of all trial applications and approvals in the EU, which will be of key importance for developers and appraisers alike. This session will consider the benefits and risks of the increasing demand in transparency of clinical (trial) data for regulators, HTA agencies, industry, and patients. The audience will be asked to participate in the debate.

USE OF REAL WORLD DATA ISSUES

IP13: BEST AVAILABLE EVIDENCE FOR HEALTH TECHNOLOGY ASSESSMENT DECISION MAKING: EFFICACY OR EFFECTIVENESS?

Space 1 (L0)

Moderator: Robert B McQueen, PhD, Health Economist, Research in Real Life (RiRL), Cambridge, UK

Panelists: Jonathan D. Campbell, PhD, Assistant Professor, Center for Pharmaceutical Outcomes Research, University of Colorado Anschutz Medical Campus, Denver, CO, USA; Pyamath Dilokthornsakul, PharmD, Doctor, Center of Pharmaceutical Outcomes Research, Naresuan University, Muang, Phitsanulok, Thailand; David Price, MD, Professor of Primary Care Respiratory Medicine, Division of Applied Health Sciences, University of Aberdeen, Aberdeen, UK
**ISSUE:** What do we mean by best available evidence in the context of health technology assessment (HTA) decision making? Public and private payers are often forced to use regulatory-driven evidence to inform coverage and reimbursement decisions – data addressing the question: “Can an intervention work in a focused and tightly controlled environment?” rather than “Does it work when used in routine care in real patients?” Cost-effectiveness analyses projecting the costs, risks, and benefits of interventions may be used to guide decision makers, such as HTA bodies, trying to select interventions that offer maximum benefit to their patients given available resources. However, little guidance is given on the relative merits of using effectiveness evidence (pragmatic trials, observational research), and to what extent, in HTA submissions. Public and private payers would like to understand not only whether an intervention works, but also whether it offers good value compared to licensed alternatives (not placebo) as they are used in real-world practice and real-world populations (not in a controlled trial environment).

**OVERVIEW:** Addressing concerns related to defining and generating best available evidence in an efficient and timely manner requires consideration to the relative strengths and weaknesses within different domains of evidence. Such HTA decision making evidence domains (i.e., health care utilization and costs, health benefits and harms) could be characterized on an effectiveness–efficacy continuum building off the Pragmatic-Explanatory Continuum Indicator Summary wheel. Panel members, along with abundant audience participation, will debate these issues. Specifically, Dr. McQueen will set the stage for tradeoffs between different HTA decision making evidence domains. Dr. Dilithornwai will draw from case examples where the HTA domains used more efficacy versus effectiveness evidence. Dr. Campbell and Dr. Price will then adopt contrasting perspectives on the pros and cons of including effectiveness versus efficacy evidence into HTA decision making domains.

**ECONOMIC OUTCOMES RESEARCH ISSUES**

**IP14: VALUING HEALTH: HAVE WE REALLY GOT IT RIGHT?**

**Space 2 (L0)**

**Moderator:** Pauline McNulty, Vice President, Patient Reported Outcomes, JGS USA Janssen Global Services, Johnson & Johnson, Raritan, NJ, USA

**Panelists:** Paul Kind, Professor, Centre for Health Economics, Management and Policy, HSE University, St Petersburg, Russia; Ben van Hout, Professor, School of Health and Related Research (ScHARR), The University of Sheffield, Sheffield, UK

**ISSUE:** The economic evaluation of healthcare interventions is nowadays an established feature of decision-making in many (perhaps most) health jurisdictions. Cost-effectiveness analysis provides (for some regulatory agencies at least) key information that helps inform their deliberations. Cost/QALY as a decision metric has entered the mainstream of debate surrounding the introduction of new and relatively expensive therapies. The growing sophistication of analytic methods over the past 25 years has helped to consolidate that position. However, concealed from public view is the troubling fact that there is no consensus amongst health economists as to how exactly we should be gauging the value of health benefits when computing QALY gains. Precisely how should we determine the “Q” in QALYs?

**OVERVIEW:** Traditional health economics teaching indicates the need for a social preference weights/utilities for QALY calculations. Agencies such as NICE lay down guidelines that differentiate between accepted methods of determining such weights and those which fail some arbitrary rule. This, when all the evidence points to the fact that different methods yield different weights. As well as the competing views as to which of several existing methods might, or should be used in QALY calculations, the agenda has been further compounded with the emergence of new metrics which offer a different pathway to salvation. Do we really need research on new methods or are we almost there with what is already to hand? If “Value in Health” is indeed at the heart of the science promoted by ISPOR and its wider membership, then we need to confront the intrinsic fault lines in health economic analysis and honestly ask if we have really got it right when it comes to valuing health benefits. This Issues Panel with an industry-moderated clash of opposing views from two research academics provides a long-denied opportunity to initiate that debate.
HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH ISSUES

IP16: OUTCOME-BASED AGREEMENTS: HIGHLY USEFUL BUT TOO DIFFICULT TO IMPLEMENT – IS THAT TRUE?
Brown 1 (L2)
Moderator: Francois Lucas, PhD, Principal Consultant, Pope Woodhead & Associates Ltd. St. Ives, UK
Panelists: Kathleen Hughes, MBA, Vice President, Health Economics and Outcomes Research, Avalere Health LLC, Washington, DC, USA; Swati Mehta, MBA, Associate Director, Pricing and Market Access, Bristol-Myers Squibb, Uxbridge, UK; Antoni Gilabert-Perramon, PhD, Managing Director of Pharmacy and Medicines, Catalan Health Service, Government of Catalonia, Barcelona, Spain
ISSUE: The need to manage uncertainty about the benefits of health technologies has increased steeply in Europe and the US, as a result of many factors such as accelerated approval of expensive innovative drugs. Performance-based (risk-sharing) agreements (PBRSAs) have been touted as a mechanism to manage this uncertainty. Experimentation has happened in the form of patient-level schemes (e.g. pay by result) and coverage with evidence development. Clinical decision-making requires evidence, however, often based on the basis that PBRSAs are usually ‘too complicated’ to implement; at the same time both payers and industry are keen to go down that route. Clear, pragmatic guidance about when and how to implement PBRSAs in the key markets is lacking but absolutely needed.
OVERVIEW: The moderator and Panelist 1 have worked on PBRSAs for years in the EU and USA, respectively. They will share their experiences and argue that there are specific circumstances when a PBRSA is warranted and feasible, and other situations when they are not. Panelist 2, a leader in creating and implementing a PBRSA policy in his region, will articulate when payers see PBRSAs can meet their needs and what practical challenges he has been resolving. Panelist 3 will defend the case that the pharmaceutical industry wants and can support payers in concrete ways to make PBRSAs work when appropriate. The audience will have the opportunity to address the panelists.

IP17: JOINT ASSESSMENTS IN EUROPE: CAN WE DO IT AND HOW?
Brown 2 (L2)
Moderator: Adrian Griffin, MSc, Vice President, HTA & Reimbursement Policy, Johnson & Johnson, Buckinghshire, UK
Panelists: Luciana Ballini, MSc, Head of Regional Observatory for Innovation, Regional Agency for Health and Social Care – Emilia-Romagna, Bologna, Italy; Wim Goetsch, PhD, Advisor International Affairs, National Healthcare Institute (ZIN), Dieren, The Netherlands; Zoe Garrett, MRes, Technical Adviser, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), London, UK
ISSUE: The benefits of having aligned health technology assessment (HTA) across Europe would include avoidance of duplication of work both for manufacturers and local (national or regional) HTA bodies - resulting in increased efficiency and ultimately in improved access for patients to effective health technologies. However there are challenges to such alignment including differences in national context and the criteria applied in assessment of value. Further, each country asserts their right to make their own decisions on coverage and many differences remain in standards and methodologies.
OVERVIEW: For the past ten years, the HTA organisations in the European network for Health Technology Assessment (EUnetHTA), have worked together to develop reliable, timely, transparent and transferable information to contribute to HTAs in their countries. Tools and approaches to support this effort have been developed, piloted and applied. An approach of comprehensive HTA, which will be discussed by Luciana Ballini, is visible in the EUnetHTA tools and procedures based on the nine domain HTA Core Model® framework. This could potentially be considered to improve the structure of early scientific advice and dialogues with the industry as well as additional evidence generation. Wim Goetsch and Zoe Garrett will, in turn, take the perspective of the rapid HTAs, developed to meet requirements for rapid Relative Effectiveness Assessment (REA). They will discuss potential use of cost-effectiveness analyses and the purpose of the evidence submission template that could be used either for joint or local assessments. The panel and the audience debate will be moderated by a representative of a pharmaceutical industry, who will facilitate the discussion towards the current progress and obstacles in the joint production of HTAs as well as pros and cons of the alignment/standardisation in HTA from the perspective of the industry, and improved patient access to effective technologies.

IP18: TO SEEK OR NOT TO SEEK PARALLEL EUROPEAN MEDICINES AGENCY (EMA)/HEALTH TECHNOLOGY ASSESSMENT (HTA) SCIENTIFIC ADVICE? THAT IS THE QUESTION
Space 1 (L0)
Moderator: Thomas J Bramley, PhD, Senior Vice President, Xcenda, Palm Harbor, FL, USA
Panelists: Ansgar Hebborn, PhD, Head, Global Market Access Policy, F. Hoffmann-La Roche AG, Basel, Switzerland; Dr. Elenon Spackman, PhD, Research Fellow, Centre for Health Economics, University of York, Heslington, York, UK; Trent McLaughlin, PhD, Vice President, Xcenda, Palm Harbor, FL, USA
ISSUE: In May 2014, EMA released draft guidance regarding best practices for seeking parallel EMA/HTA scientific advice with the assertion that “strong interaction between regulators and HTA bodies is critical to enable innovation to reach patients, and ultimately for the benefit of public health.” In theory, a single forum where both the views of EMA and HTA can be expressed could accelerate development plans and ultimately speed reimbursement across participating regions. Still, EMA and HTA bodies have distinct purposes with EMA seeking to ensure consumer protection with a focus on safety and efficacy while HTA bodies seek to serve the public good by assessing comparative clinical and cost-effectiveness. Even the focus of HTA bodies varies greatly in terms of what constitutes clinical and cost-effectiveness further compounding the complexities of parallel advice. The issue explored here is how to best seek (or potentially not seek) parallel advice from EMA and HTA given the differences in focus across HTA bodies and EMA.
OVERVIEW: Dr. Ansgar Hebborn will highlight the benefits and shortcomings of seeking parallel advice from the perspective of a pharmaceutical manufacturer. Dr. Elenon Spackman will speak to the practical considerations of meeting the needs of HTA bodies in a clinical trial program. Dr. McLaughlin will speak to the benefits and potential pitfalls of seeking advice by individual HTA bodies.

ECONOMIC OUTCOMES RESEARCH ISSUES

IP19: HOW DO WE EVALUATE TECHNOLOGIES WHICH ARE NOT COST-EFFECTIVE AT A ZERO PRICE?
Space 2 (L0)
Moderator: Ron Akhurst, PhD, Strategic Director, BresMed Health Solutions Ltd., Sheffield, UK
Panelists: Sarah Davis, MPhys, Senior Lecturer in Health Economics, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; Gavin Lewis, MSc, Head of Pricing and Market Access, Region Europe, Roche, Basel, Switzerland; Janet Robertson, BSc, BA, DipPresSci, Associate Director, Technology Appraisals, Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE), London, UK
ISSUE: The acquisition cost for new health technologies is usually a key determinant of whether the technology is considered to be cost-effective by Health Technology Assessment (HTA) agencies. However, there are several scenarios under which clinically effective technologies may be found not to be cost-effective even if the acquisition price is zero. This happens because the new technology increases the costs incurred during the patient’s lifetime by increasing some form of health care resource use unrelated to the acquisition cost of the technology. In some cases, that additional resource use is clearly related to the technology being evaluated, such as when new technologies are used in combination with existing high cost treatments. In other cases it may occur simply because the technology extends survival in a patient population which happens to have high health care resource use. This raises interesting questions regarding whether it is right to include that additional resource use within the economic evaluation from a methodological and/or ethical perspective. Rejecting such technologies may have implications for future investments in innovative technologies in these populations which may be unacceptable.
OVERVIEW: The three panelists are all actively involved in HTA and each will discuss the implications of this issue from their differing perspectives. Sarah Davis will introduce the topic by providing a summary of the scenarios in which this issue occurs and describing the pros and cons of some alternative approaches which could be adopted, from an academic perspective. Gavin Lewis will discuss the implications for innovation and incentives from a pharmaceutical perspective. Janet Robertson will discuss the implications for HTA organisations which use cost-effectiveness analysis to inform their guidance. The audience will be invited to ask the panel members questions and participate in the debate.

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH ISSUES

IP20: PATIENT-REPORTED OUTCOMES: CAN THEIR USE IN OBSERVATIONAL ("REAL-WORLD") RESEARCH BE CONSIDERED INTERVENTIONAL?

Brown 2 (L2)
Moderator: Matthew Reaney, CPsychol, MSc, Senior Research Scientist, ERT, Peterborough, UK
Panelists: Erin Tomaszewski, MS, Clinical Outcomes Research Scientist, Quintiles, Durham, NC, USA; Olivier Chassany, PhD, Director, Patient-Centered Outcomes Research, Paris, France

ISSUE: Can patient-reported outcomes (PRO) data be collected in the “real world” without impacting on participant behavior?

OVERVIEW: Regulatory, payer and healthcare stakeholders are increasingly requesting observational research to confirm safety, efficacy and value inferred from clinical trials among patients prescribed a new product in the “real world” (i.e. during routine clinical care). Prospective observational studies are often best placed to answer the questions that remain at marketing authorization. Such studies afford the opportunity to administer Patient-Reported Outcome (PRO) questionnaires to elicit the patients’ perspective on their disease and treatment. PRO data allows researchers to demonstrate incremental value afforded by a new product. Some have expressed concern that the administration of PROs in observational research is, in-and-of itself, interventional, due to potential modifications in patient-provider communication and patients’ destabilization. Others maintain that PROs are not interventional as the interaction is between the patient and the questionnaire, and perhaps provide a better indication of product impact when administered in a clinical practice environment rather than a clinical trial. This debate is an important one, as qualification of PROs as interventional or not, will impact the classification of the “observational” study. This has safety, management, ethical and utility implications. Moreover, new European regulation on clinical trials of medicinal products does not cover observational studies. This session will first present the regulatory definition of what can be considered an observational vs. an intervention study, and highlight the relevance and importance of both research types. Next a debate will be conducted, with both perspectives represented via empirical presentations of case studies. The chair will then explore whether PROs should always or ever be considered interventional, and/or whether this differs by endpoint, context of use, disease, and reactivity to monitoring. The audience will be encouraged to share examples from their own experience and give their own perspectives.
W1: DEFINING AND VALUING INNOVATION IN ONCOLOGY

**Gold (L2)**

**Discussion Leaders:** Michael Drummond, MCom, DPhil, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; Alistair Mcguire, PhD, Professor of Health Economics, London School of Economics, London, UK; Monique Martin, PharmD, MSc, MBA, Vice President & General Manager HEOR Europe, MAPI, Uxbridge, UK; Elizabeth Jones, MSc, Project Leader, HEOR Europe, MAPI, Uxbridge, UK

**PURPOSE:** To compare and evaluate how regulators and payers define and reward innovation.

**DESCRIPTION:** Rising drug costs and budgetary constraints have led decision makers to be restrictive in the acceptance of new drugs and are increasingly asking for a demonstration of innovation. In cancer care this is especially important as many of these treatments are expensive and often have limited data on which to base their economic value. In this workshop we will focus on how regulators define and reimburse innovative therapies. We will give examples of accelerated approval, fast-track, priority review and breakthrough therapy status. In addition, we will adopt a decision maker’s perspective, where we will distinguish between types of innovation in particular a novel innovation which relates to a new product that alters the existing market and will create a new demand, and an incremental innovation which is associated with the improvement of an existing class of treatments. Issues relating to surrogate endpoints and the demonstration of innovation, will also be addressed. Furthermore we will attempt to show whether innovative status as defined by different regulators has market impact. Finally we will link these issues to other disease areas where innovation costs are high and product value is difficult to define. We will ensure audience participation by providing the product profiles of two imaginary products, characterizing breakthrough therapy and incremental innovation, at the room entry and we will ask the audience to rank market impact based on these product profiles in terms of likely accepted reimbursed price, volume and clinical importance.

W2: THE PUB & THE P-SUB: A POTENTIAL FRAMEWORK DEVELOPED TO ASSESS THE NEED FOR AND DESIGN OF MANAGED ENTRY AGREEMENTS FOR NEW DRUGS

**Brown 1-2 (L2)**

**Discussion Leaders:** Sabine Grimm, MSc, PhD Candidate, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; Alan Brennan, PhD, Professor of Health Economics and Decision Modelling, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; Mark J. Sculpher, MSc, PhD, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; Johan L. Severens, PhD, Professor of Evaluation in Health Care, Institute of Health Policy and Management, Institute of Health Policy & Management, Erasmus University Rotterdam, Rotterdam, The Netherlands

**PURPOSE:** To present and discuss a framework developed to assess the need for and design of managed entry agreements for new drugs.

**DESCRIPTION:** Managed Entry Agreements (MEAs) can be used by reimbursement authorities and manufacturers to agree a process for recommending new drugs that can include agreed price reductions and/or further research to be conducted. The NICE Decision Support Unit was commissioned to develop a framework that could potentially be used for assessing proposed MEAs within NICE technology appraisals. In this workshop the speakers in turn will: 1.) Present the framework and its application to several exemplary case study results. The methods are simple extensions / representations of the results from a standard cost-effectiveness analysis with probabilistic sensitivity analysis. They calculate the “Payer Uncertainty Burden (PUB)” for the decision and the “Payer Optimality Gain (POG)” for the option which is most cost-effective. For options which are not the most cost-effective, they estimate the “Payer Sub-optimality Burden (PSB)” and the “Payer Sub-optimality AND Uncertainty Burden (PSUB)”.

W3: ADJUSTING FOR TIME-DEPENDING CONFOUNDING AND CROSSOVER BIAS IN OBSERVATIONAL STUDIES AND CLINICAL TRIALS: PURPOSE, METHODS, AND ACCEPTANCE IN HTA

**Brown 3 (L2)**

**Discussion Leaders:** Felicitas Kuehne, MSc, Senior Scientist, Public Health and Health Technology Assessment, UMIT, Hall I.T., Austria; Uwe Siebert, MD, MPH, MSc, ScD, Professor, Department of Public Health & HTA/ONCYTROL, Area 4 HTA & Bioinformatics/Harvard T.H. Chan School of Public Health, Center for Health Decision Science, Department of Health Policy & Management, Harvard Medical School, Institute for Technology Assessment & Department of Radiology, Hall I.T., Austria; Nicholas Latimer, PhD, Senior Research Fellow in Health Economics, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; Lars Beckmann, PhD, Research Fellow, Institute for Quality and Efficiency in Healthcare (IQWiG), Cologne, Germany

**PURPOSE:** In this workshop, three invited speakers will provide an overview of causal methods. We present the purpose and methods of adjusting for time-depending confounding in observational studies and adjustment for crossover in randomized clinical trials (RCTs) in the context of health technology assessment (HTA). We discuss the indications and data requirements for applying these methods and discuss how well they are accepted in science and for approval from regulatory and reimbursement agencies.

**DESCRIPTION:** Observational studies and RCTs need causal methods to estimate a valid causal effect. Causal methods are needed if there is confounding-by-indication in observational studies or when ITT analyses lead to biased effect estimates in RCTs with noncompliance or treatment switching. Since first HTA agencies have accepted and requested the use of causal methods, a paradigm shift is taking place, and the selection of the appropriate method has become crucial to yield patient access to innovative treatments. The workshop has three parts: 1.) Prof. Uwe Siebert will take the educational perspective, introducing the concepts and methods of causal analysis and presenting case examples demonstrating how inadequate analysis can yield inappropriate results, impacting recommendations made by HTA agencies (e.g. NICE). 2.) Dr. Nicholas Latimer will take the scientific perspective, explaining the theoretical background and comparing different methods (e.g., rank preserving structural failure time models, marginal structural models, two stage approach), and discussing recommendations regarding when to use which methods. 3.) Dr. Lars Beckmann will take an agency-perspective, discussing the acceptance and barriers of statistical methods to approach treatment switching in RCTs in the process of drug approval and how treatment switching can influence study design, analytic strategy, approval, and the HTA process. We will provide an outlook to what should be done to move the field forward and will invite the audience to participate in this discussion.
都不要依赖比例风险假设，以及参数性质的违反会导致严重偏移估计值。

由于尾部生存函数对其预期生存有重大影响，因此需要一个对应的生存函数来比较预期PFS和OS。

试验特定常数风险比的元分析可以被用于计算元分析模型，这些元分析模型可以被用于元分析模型的比较。

成本-效果分析中的元分析模型可以克服不完整的证据网络。

This workshop will provide guidance regarding the selection of meta-

DESCRIPTION:

STC and MAIC can overcome incomplete evidence networks

where lack of comparative trials or common comparators prohibit comparisons

between some of the treatments with an NMA. Even with a complete network,

heterogeneity between studies may compromise reliability NMA. STC and MAIC

can address such heterogeneity, especially when it is attributable to differences

in study populations. While conceptually similar, the two approaches differ in the

methodology they use to balance the populations. STC uses predictive equations

to generate adjusted outcomes in the comparator population, while MAIC achieve

this by reweighting patients in one trial to match the profile of the other's

population. An example in cardiovascular disease will be used to illustrate the

analytical steps of each approach, highlighting the assumptions being invoked.

A notable feature of the example is the studies do have common comparator

arms; this offers an opportunity to assess whether there is any heterogeneity

due to factors beyond the population profiles, and how this may be leveraged in

the analyses. Furthermore, common comparator arms also allow a contrasting of

results from STC and MAIC with an NMA. The concepts will be generalized beyond

the example to help address questions such as, when STC or MAIC should be

applied and how this may be leveraged in the analyses.

PURPOSE:

This workshop will provide guidance regarding the selection of meta-

analysis models for PFS and OS that provides a compromise between statistical criteria of

validity and clinical plausibility.

The workshop will conclude with an interactive session in the form of a multiple choice quiz where the proposed

guidance needs to be applied to realistic examples.

PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH

W6: ASSESSING MEDICATION ADHERENCE: PATIENT-REPORTED, CLINICAL, PHARMACOEPIDEMICIOLOGIC, AND ECONOMIC APPROACHES

Space 3 (LO)

Discussion Leaders: Sarah Clifford, PhD, Director, ICON Commercialisation and Outcomes, ICON Clinical Research, LLC, San Francisco, CA, USA; Lina Eliasson, PhD, Lead Outcomes Researcher, ICON PRO, Oxford, UK; RA Elliott, PhD, Lord Trent Professor of Medicines and Health, Social Research in Medicines and Health School of Pharmacy, University of Nottingham, Nottingham, UK; Shelagh Szabo, MSc, Director & Head of Evidence Generation, Redwood Outcomes, Vancouver, BC, Canada

PURPOSE:

The purpose of this workshop is to describe barriers to accurately

estimating adherence; discuss approaches to assessing and evaluating adherence from the clinical, patient-reported, pharmacoeconomic, and economic perspectives; and develop study designs to robustly measure adherence using real-world examples.

DESCRIPTION:

Although adherence to appropriately prescribed medications is a key contributor to effectiveness, non-adherence remains common. It is estimated that approximately 50% of patients may not take their medications as prescribed, which can impact the success of treatment and relevant clinical and patient-reported outcomes, and increase the economic burden. Understanding adherence is important not only for individual patient disease management, but also for accurately evaluating the benefits and risks of new vs existing therapies. However, accurately estimating medication adherence is challenging because of selection and reporting biases that impact study findings, in addition to inaccuracies in the adherence measures themselves. In many diseases there is little good quality evidence linking adherence to patient outcomes and associated economic impact, required for assessing the cost effectiveness of adherence-enhancing interventions.

This workshop will provide a background for participants on adherence assessment and evaluation methods from a number of disciplines, including state-of-the-art approaches or the novel use of existing data sources. The strengths and limitations of the approaches will be reviewed. While working within small groups, workshop participants will review, critique, and appraise existing study designs, and propose novel strategies to address adherence-related study questions. Researchers interested in understanding data and methods available to assess and evaluate adherence would benefit from participating in this workshop.
W7: MARKET ACCESS 2020: WHAT ARE THE NEXT CHALLENGES?

**Gold (L2)**

**Discussion Leaders:** Meriem Bouslouk, PhD, MSc, Officer, Pharmaceuticals Department, Federal Joint Committee (G-BA); Berlin, Germany; Ian Mueller-Berghaus, MD, Paul-Ehrlich-Institute (PEI); Langen, Germany; Antoni Gilabert-Perramon, PhD, Managing Director of Pharmacy and Medicines, Catalan Health Service, Government of Catalonia, Barcelona, Spain; Mondher Toumi, MD, MSc, PhD, Professor of Public Health, Department of Public Health, Aix-Marseille University, Marseille, France

**PURPOSE:** In this workshop, the speakers propose to confront different perspectives: an academic professor, a national HTA from the G-BA (Germany), a regional payer from Spain (Catalonia) and a regulator from Paul-Ehrlich-Institut (Germany) in order to share vision on future market access models in place or in discussion to cope with the evolving pharmaceuticals environment. Challenges will include: (1) Pressure on health budgets; (2) Technological and scientific advances, i.e. advanced therapeutic medicinal products, personalized medicines, digital medicine; (3) Joint regulators/payers initiatives, multi-HTA collaboration; (4) Increased payer risk-aversion and increasingly limited information at launch; (5) Medicine; (3) Joint regulators/payers initiatives, multi-HTA collaboration; (4) Increased payer risk-aversion and increasingly limited information at launch; (5) Development of integrated healthcare (IH); (6) Growing prevalence of chronic conditions; (7) Increased access inequity between European Union (EU) Member States (MS).

**DESCRIPTION:** Adaptive pathways and limited evidence at time of launch may enhance coverage with evidence development. More pragmatic clinical trial designs may be considered to cope with concomitant development of companion diagnostics, segmentation of patients, targeted therapies. Adaptive pathways may become standard approach. Cost-containment measures will fall under MS parliaments’ supervision. Fast development of electronic communication will allow online monitoring of drug utilisation patterns. Post-launch observational studies will become unavoidable to meet regulators and payers’ expectations. Pan-European HTA coordination could lead to one single European HTA body assessing drugs prior to national HTA. Managed entry agreements, ambulatory DRG, and bundled payments will be frequent. IF will expand shifting payer’s role to healthcare providers. Differential pricing will address inequity across EU MS. Based on their long experience, the contributors will explain how extended collaborations and interactions between key stakeholders will become a critical issue to maintain the sustainability of healthcare systems, in a fast evolving environment. Contributors will involve the audience by encouraging them to provide input and real life experience to enlarge the contribution to this debate.

W8: EVIDENCE SYNTHESIS BASED ON AGGREGATE AND INDIVIDUAL-LEVEL DATA: CONSIDERATIONS FOR USE IN HTA DECISION MAKING

**Brown 3 (L2)**

**Discussion Leaders:** Timothy Reason, MSc, Senior Consultant, Real-World Evidence Solutions, IMS Health, London, UK; Pedro Saramago Goncalves, MSc, PhD, Research Fellow, Centre of Health Economics, University of York, Heslington, York, UK; Yumi Asukai, MSc, Director, R&D Value Evidence Analytics, GSK, Uxbridge, UK; Keith R Abrams, PhD, Professor of Medical Statistics, Department of Health Sciences, University of Leicester, Leicester, UK

**PURPOSE:** This workshop will discuss potential dangers of relying on evidence synthesis from Network Meta-Analysis (NMA) based solely on aggregate data in informing comparative effectiveness, and the impact of such use on decision-making. We will highlight potential solutions and current barriers to resolution to initiate a dialogue among the community for responsible evidence generation.

**DESCRIPTION:** Lack of head-to-head trials between relevant comparators has led to increased use of NMA techniques for establishing comparative effectiveness. These techniques have become especially relevant in economic evaluation and HTA to inform resource allocation at the national level. Realistically, most NMAs are conducted using aggregate data, while key steps can be taken to address potential biases, such as adjustment for effect modifiers and selecting appropriate studies or sub-populations to minimise heterogeneity, there are still several issues that cannot be adequately addressed without Individual Patient Data (IPD). Tim Reason will review current standards of NMAs and how to correct for potential bias, as well as the advantages of using IPD in place of aggregate data in addressing ecological bias and study-level confounding. Pedro Saramago will discuss how the use of IPD can increase power for sub-group analyses and allow richer stratification of patients for decision making, potentially allowing appropriate judgements to be made for particular subgroups. Yumi Asukai will discuss the impact of using results of evidence syntheses in economic models and the pros and cons of having IPD-based NMAs, including decreased uncertainty, both structural and parameter. Lastly, Keith Abrams will summarise the issues raised in the wider context of policy decisions. The audience will be asked to comment on hypothetical case studies and how the use of IPD could improve the ultimate decision; discussion will centre around advantages of having access to IPD in establishing comparative effectiveness for the purposes of health care policy decision making.

USE OF REAL WORLD DATA

W9: DEVELOPMENT OF EVIDENCE PACKAGES FOR REGULATORY AND REIMBURSEMENT SUBMISSIONS IN RARE DISEASES: REAL-WORLD EXAMPLES

**Space 1 (L0)**

**Discussion Leaders:** Nicola Bonner, MSc, Senior Research Manager, EDOA, Adelphi Values Ltd, Bollington, UK; Alexandra Bowden, PhD, Senior Manager, Ultragrenyx Pharmaceutical Inc., Novato, CA, USA; Vasudha Bal, MSc, MBA, Director, Patient Reported Outcomes, Worldwide Health Outcomes, Value & Access, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; Anne Kilburg, MSc, Principal Consultant, Wellmera AG, Basel, Switzerland

**PURPOSE:** This workshop will highlight the importance of, and challenges associated with development of evidence such as suitable endpoints, Clinical Outcome Assessments (COAs) and comparators in rare diseases using real-world examples.

**DESCRIPTION:** Increasing numbers of rare diseases are being recognized and more medicines to treat them being developed. There are several unique challenges for developing evidence packages in rare diseases such as the paucity of information on patient populations, disease progression and appropriate COAs. As with all clinical development programs, disease specific COAs are an important part of assessing signs and symptoms of rare diseases and treatment response. The objectives will be achieved through four presentations of approximately 12 minutes and audience questions. Firstly, Vasudha Bal will present the overall challenges of collecting data to support registration and reimbursement. She will outline the key areas where collecting such evidence could be particularly difficult. Nicola Bonner will then discuss the challenges associated with developing COAs, and special considerations associated with clinical trials and regulatory approaches in rare diseases. This segment will involve audience members sharing examples of challenges associated with conducting research in rare diseases. Anne Kilburg will discuss the evidence needs and requirements for HTA/payer bodies for a positive value assessment and reimbursement. This section of the workshop will involve an interactive exercise with the audience to vote blinded case studies in terms of their value assessment/reimbursement outcomes. Alexandra Bowden will then share an example of a healthcare professional administered COA for assessment of physical functioning limitations associated with a rare genetic disease. This section of the workshop will involve audience members trying some of the activities assessed by the instrument and discussing the challenges associated with ensuring consistent assessment of the activities. The session will close with audience questions and sharing their own examples of work in rare diseases.
**CLINICAL OUTCOMES RESEARCH**

**W10: MOVING THE SCIENCE FORWARD: TACKLING KEY PSYCHOMETRIC AND METHODOLOGICAL ISSUES FACING THE FIELD OF CLINICAL OUTCOME ASSESSMENT**

**Space 2 (LO)**

**Discussion Leaders:** Tara Symonds, PhD, COA Strategy Lead & Partner, Clinical Outcomes Solutions Ltd., Folkestone, Kent, UK; Kathleen W. Wyrwich, PhD, Executive Director, Center of Excellence, Outcomes Research, Evidera, Bethesda, MD, USA; Antoine Regnault, PhD, Research Director, HEOR & Strategic Market Access, Mapi, Lyon, France; Stephen Joel Coons, PhD, Executive Director, PRO Consortium, Critical Path Institute, Tucson, AZ, USA

**PURPOSE:** The purpose of this workshop is to present several key unresolved methodological issues facing the regulatory and scientific community in the field of clinical outcome assessment (COA) and to discuss insight gained from initial deliberations aimed at achieving scientific consensus and resolution.

**DESCRIPTION:** A group of measurement specialists convened to discuss issues identified by academics, industry, and regulators as scientifically challenging in the context of developing, evaluating, and interpreting COAs. The issues addressed by this panel included: 1) Methods for determining clinically meaningful change e.g. What defines a good anchor? Are distribution-based methods useful? What is the appropriate role for cumulative distribution functions? Are qualitative studies a more direct way of deriving meaningful change from patients’ and clinicians’ perspectives? 2) Quantitative assessment of cross-cultural differences e.g. If a COA is not quantitatively equivalent cross-culturally, what are the solutions? When is absence of equivalence an important issue? 3) Use of mixed methods research in instrument development e.g. What is the value of mixed methods research in COA tool development? Can it provide a more efficient way of developing content for new measures? When is a qualitative sample sufficient for exploratory quantitative analysis? 4) Context effects and use of computer adaptive testing (CAT) e.g. Do context effects have the potential to introduce enough response bias to necessitate the time and expense of additional quantitative research? How to address the perceived limitation regarding use of CAT e.g. heterogeneity, and concept coverage/content balance, and selected/non-selected response bias? The discussion leaders will outline the issues and describe the current consensus landscape, noting how future research will move the field towards resolution. Discussion leaders will engage attendees to share their perspectives on the most relevant and effective approaches to addressing each of the issues, as well as to provide insight gained from their own research.

**ECONOMIC OUTCOMES RESEARCH**

**W11: TRANSLATING PHARMACOMETRICS TO PHARMAECONOMICS**

**Space 3 (LO)**

**Discussion Leaders:** Richard J. Willke, PhD, Vice President, Outcomes & Evidence Lead CV/Metabolic, Pain, Urology, Gender Health, Global Health & Value, Pfizer, Inc., New York, NY, USA; Scott Marshall, PhD, Senior Director, Pharmacometrics, Global Clinical Pharmacology, Pfizer, Inc., Sandwich, UK; John Posnett, DPhil, Vice President, Health Economic Modelling Unit, PAREXEL International, London, UK; Julia F Siejkso, PhD, Assistant Professor, Pharmaceutical Health Services Research, University of Maryland School of Pharmacy, Baltimore, MD, USA

**PURPOSE:** A key aspect of any health economic model is the way that treatment outcomes are determined. The purpose of this workshop is to present a practical, step-by-step example of how pharmacometric findings may inform health economic model inputs. We will: 1) Present an overview of pharmacoeconomic models, 2) Illustrate how a health economic model structured to be consistent with pharmacometric findings can be a powerful tool to project the clinical and health economic results of a clinical trial or other health intervention on specific populations, and 3) Engage the audience in a discussion about evaluations of potential cost-effectiveness and the probability of a drugs’ success in later-stage clinical trials.
WORKSHOPS – SESSION III: TUESDAY, 10 NOVEMBER: 16:30-17:30

W13: THE ROLE OF VALUE OF INFORMATION IN HTA: ARE WE MISSING AN OPPORTUNITY?

Brown 3 (L2)
Discussion Leaders: Gianluca Baio, PhD, Reader in Statistics & Health Economics, Statistical Science, University College London, London, UK; Nicky J. Welton, MSc, PhD, Reader in Evidence Synthesis, School of Social and Community Medicine, University of Bristol, Bristol, UK; Mark Strong, PhD, Clinical Senior Lecturer in Public Health, School of Health and Related Research, University of Sheffield, Sheffield, UK; Anna Heath, BSc, PhD Student, Statistical Science, University College London, London, UK

PURPOSE: The purpose of this workshop is to: (i) demonstrate, with examples, recent developments in the computation of Expected Value of Partial Perfect Information (EVPPI); and (ii) to discuss the potential role of Value of Information (VoI) in assessing key drivers of decision uncertainty and the need for further research.

DESCRIPTION: In health economic evaluations, the EVPPI is a measure of the sensitivity of a decision to uncertainty in individual model inputs. The EVPPI can therefore help decision makers focus on the key parameters driving decision uncertainty and point towards areas where there truly is a need for further research. Until recently, the EVPPI was computationally intensive to calculate and required a high level of technical expertise. However, recent statistical developments have allowed approximations of the EVPPI that are accurate, fast, efficient and straightforward to compute. Now the technical barriers to computing Vol have been removed there is an opportunity to use the methods routinely in HTA. The workshop will begin with Dr Baio who will give an introduction to EVPPI and the need for efficient computational methods, by presenting some examples to illustrate how the EVPPI can be used within an HTA context. Next, Dr Strong will present a novel non-parametric regression method for approximating the EVPPI. He will illustrate the method using the “SAVI” web app, a simple user interface for the non-parametric regression method which requires only the probabilistic sensitivity analysis sample. Miss Heath will present a further development to the non-parametric regression method and will demonstrate the ease with which the EVPPI can be computed using the R package BCAE. We finish the workshop with a discussion, led by Dr. Welton, of the facilitators and barriers to the routine adoption of Vol calculation in HTA now that computational difficulties have largely been solved.

W14: ORPHAN DRUG EVIDENCE REQUIREMENTS FOR POSITIVE HTA RECOMMENDATIONS

Gold (L2)
Discussion Leaders: Josie Godfrey, MA, Associate Director, Highly Specialised Technologies, National Institute for Health and Care Excellence (NICE), London, UK; François Meyer, MD, Advisor to the President, International Affairs, French National Authority for Health (HAS), Paris, France; Mondher Touni, MD, MSc, PhD, Professor of Public Health, Department of Public Health, Aix-Marseille University, Marseille, France; Meriem Bouslouk, PhD, MSc, Officer, Pharmaceuticals Department, Federal Joint Committee (G-BA), Berlin, Germany

PURPOSE: In this workshop, the speakers explore how the available degree of evidence for orphan drugs influences health technology assessment (HTA) outcomes and decision-making in three different European orphan drug assessment procedures and critically discuss the results with the audience on the basis of concrete current examples to enable recommendations for future HTA.

DESCRIPTION: With the introduction of the Regulation (EC) No 141/2000 on orphan medicinal products, specific criteria have been established to ensure a scientific designation of pharmaceuticals as orphan drugs within the European Union. These products undergo different market access procedures and incentives in the European countries, including different points in time for their patient’s availability, different national policies for benefit assessment and different coverage. Because of the high prices and increasing budget impact of orphan drugs, health technology assessments, in their function as the basis for related reimbursement, are of crucial interest for access to these pharmaceuticals. A generic HTA decision framework happens to be inappropriate in some countries, especially when driven by incremental cost-effectiveness ratio. The contributors will give an overview of current approaches of evaluating orphan drugs by different HTA bodies with a focus on evidence requirements in specific countries like France, Germany and UK. Examples will be used to illustrate the heterogeneity of decisions across Europe and make recommendations to maximize chances to achieve positive HTA outcomes. The moderator Professor Touni will stimulate the audience to contribute to the debate by discussing their experience with current orphan drug HTA outcomes.

USE OF REAL WORLD DATA

W15: SAMPLE SIZE ESTIMATION AND POWER CALCULATION FOR PROSPECTIVE OBSERVATIONAL STUDIES

Space 2 (L0)
Discussion Leaders: Eric Gemmen, MA, Senior Practice Leader, Epidemiology & Outcomes Research, Real-World & Late Phase Research, Quintiles, Inc., Rockville, MD, USA; Mark J Nixon, MSc, PhD, Director, Chilli Consultancy, Salisbury, UK

PURPOSE: To highlight challenges and offer solutions to sample size estimation and power calculation for observational studies and patient registries, through use of numerous case examples and live calculations.

DESCRIPTION: Unlike randomized controlled trials (RCTs), prospective observational studies and patient registries typically address objectives rather than test specific hypotheses. Nevertheless, estimation of sample size is an important part of the planning process for these studies. A minimum sample size and power is required to allow for adequate exploration of the objectives and to ensure sufficient generalizability of the results. Sample size estimation for observational studies is more complex than sample size calculation for RCTs; subgroup analyses and modeling are to be expected in observational studies, and these analysis methods require more assumptions and larger sample sizes. On the other hand, sample sizes must not be so large as to raise concern that the observational study includes an unnecessarily high number of sites and patients, which is particularly true where a specific commercial product is being observed. This workshop will provide examples/case studies of sample size estimations performed for a variety of prospective observational studies with an array of objectives, including burden of illness, comparative effectiveness, comparative safety and personalized medicine. We will focus on sample size estimation methods for observational studies that take the following analysis techniques into account: 1.) Outcome comparisons against historical comparators and historical controls. 2.) Propensity score matching to support comparisons of cohorts. 3.) Investigation of factors that influence outcomes within subgroups. 4.) Multiple comparison adjustments to support comparisons between multiple study sites and multiple patient types across multiple time points. 5.) Time-to-event analyses including a) disease progression or remission, c) major adverse cardiac event, etc. 6.) Re-estimation of sample size based on interim results. Audience input based on experience will be encouraged throughout the session, which will include live use of sample size estimation software.

W16: RETROSPECTIVE HEALTH OUTCOMES RESEARCH AND HEALTH-ECONOMIC EVALUATION BASED ON REAL-WORLD DATA ANALYSES IN EUROPE: DATA AVAILABILITY, STRENGTHS AND LIMITATIONS, AND DATABASE-SPECIFIC CONSIDERATIONS

Space 3 (L0)
Discussion Leaders: Thomas Wilke, PhD, Partner, Ingress-Health, Wismar, Germany; Myrthe P. P. van Herk-Sukel, PhD, Manager, Research Department & Epidemiologist, PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands; Andreas Fuchs, PhD, Consulting Pharmacist, AOK PLUS, Dresden, Germany; Wilhelmine Meeraus, MSc, Research Scientist, Medicines and Healthcare Products Regulatory Agency, The Clinical Practice Research Datalink, London, UK

PURPOSE: There is a growing need to obtain real-world evidence/outcomes data in numerous indications. Retrospective database studies seem to be a fast and rather cost-effective option to collect these data. However, there may be disadvantages of database studies as well, i.e. because of limited availability of clinical data (in some databases), the mostly retrospective nature of data, non-representativeness of some databases and difficulty in assessing confounders. In this workshop, we
will discuss these issues in four sessions based on a general overview of available retrospective health databases across Europe.

**DESCRIPTION:** In the first panel presentation, Thomas presents results of a benchmarking of available non-disease specific health care databases (both claims and GP-/specialist databases) across Europe. He also discusses strengths/limitations of retrospective database analyses with respect to different disease areas and different study objectives. Andreas will discuss specifics of German claims data (available variables, strengths and weaknesses). Specifically, he will describe how to access German claims data and will discuss reliability of German claims information based on an example study in diabetes mellitus 2 patients. Wilhelmine will discuss specifics of the UK GP-based CPRD database which can also be linked to specific other databases, e.g. the HES hospital database. They will also discuss strengths and weaknesses of this widely used retrospective health database for health outcomes research, with a focus on diabetes recording and treatment. Finally, Myrthe van Heek-Sukel will discuss specifics of the PHARMO Database Network which is a population-based network of healthcare databases and combines data from different healthcare settings in the Netherlands. She will also present a case example in the area of Oncology. Interactive element: The discussion between participants will be about the value of combining data of different datasets in different countries for observational research, but also for HTA purposes.

**ECONOMIC OUTCOMES RESEARCH**

**W17: CHALLENGES AND SOLUTIONS TO SUCCESSFULLY DETERMINE REAL-WORLD COST-EFFECTIVENESS**

**Space 1 (L2)**

**Discussion Leaders:** Saskia de Groot, MSc, Researcher, Institute of Health Policy & Management, Institute for Medical Technology Assessment (iMTA), Erasmus University Rotterdam, Rotterdam, The Netherlands; Hedwig M. Blommestein, MSc, Researcher, Institute of Health Policy & Management, Institute for Medical Technology Assessment (iMTA), Erasmus University Rotterdam, Rotterdam, The Netherlands; Margreet G. Franken, PhD, Researcher, Institute for Medical Technology Assessment (iMTA), Erasmus University Rotterdam, Rotterdam, The Netherlands; Annet F.M. van Abeelen, PhD, Pharmaco Economics & Access Manager, Health Economics and Business Development, Roche Pharmaceuticals, Nederlands, Woerden, The Netherlands

**PURPOSE:** Real-world cost-effectiveness analysis (RW-CEA) is often complicated by great heterogeneity and non-randomised treatment. The aim of this workshop is to share insight into methods to appropriately deal with incomparability issues including propensity score matching (PSM), discrete event simulation (DES), and data synthesis. Strengths and limitations of these methods will be discussed from a theoretical and empirical point of view.

**DESCRIPTION:** As opposed to trial patients, real-world patients generally have a worse prognosis, more comorbidities, and are older. Therefore, there is a growing interest in real-world evidence to complement evidence from trials. However, RW-CEA is complicated by incomparability issues. Failure to account for these issues may lead to biased results and incorrect conclusions. This workshop focuses on three methods: PSM, DES, and data synthesis. The potentials and pitfalls of each method will be discussed by sharing theoretical and empirical insights based on our experiences in performing RW-CEA. First, the potential of PSM will be illustrated by matching real-world patients to create comparable groups for a RW-CEA in non-Hodgkin lymphoma. Second, the DES method will be explained using examples from two disease models spanning multiple lines of treatment (two and three treatment lines in renal-cell carcinoma and multiple myeloma, respectively). Third, data synthesis will be clarified using a RW-CEA for chronic lymphocytic leukemia in which trial data was used to determine progression-free survival and registry data was used to determine post-progression survival. The workshop will focus on the extent to which the three methods provide useful, valid and reliable information to healthcare decision makers, facilitate evidence-based decision-making, and ultimately improve health outcomes. An interactive discussion will encourage audience participation to contribute to further understanding whether it is feasible to calculate real-world cost-effectiveness.
USE OF REAL WORLD DATA

W19: ESTIMATION AND PREDICTION OF RELATIVE EFFECTIVENESS USING REAL-WORLD EVIDENCE: CASE STUDIES

Brown 1 (L2)

Discussion Leaders: Keith R Abrams, PhD, Professor of Medical Statistics, Department of Health Sciences, University of Leicester, Leicester, UK; Reynaldo Martina, PhD, Research Associate, Department of Health Sciences, University of Leicester, Leicester, UK; Eva-Maria Didden, PhD, Researcher, Institute of Social and Preventive Medicine, University of Bern, Bern, Switzerland; Sandro Gsteiger, PhD, HTA Statistician, MORSE - Health Technology Assessment Group, F. Hoffmann-La Roche Ltd, Basel, Switzerland

PURPOSE: This workshop, organized by members of the IMI GetReal project, will demonstrate several statistical and mathematical approaches that incorporate real-world evidence (RWE) into the estimation and prediction of relative effectiveness pre-launch. It will provide a forum for workshop participants to both discuss the relative merits of the various approaches and their own experiences of using RWE in HTA. The methods will be illustrated with applications from various indications, with a special focus on rheumatoid arthritis (RA).

DESCRIPTION: Incorporating RWE into the drug development process pre-launch is receiving growing interest from pharmaceutical companies, regulators, and payers alike. Health technology assessment and reimbursement decisions could benefit from methods which are able to estimate and predict relative effectiveness of treatments at the time of launch. This workshop presents statistical and mathematical approaches that combine randomized controlled trials (RCT) data and RWE to inform HTA. In the first session, Dr. Martina will discuss how data from registries and RCTs can be used to estimate relative effects of second-line use of treatments in a network meta-analysis context. In the second session, Dr. Didden will present a predictive model that incorporates data from both RCTs and registries to bridge the efficacy-effectiveness gap, i.e. to generalize results observed in RCTs to a real-world setting. In the third session, Dr. Gsteiger will discuss potential applications and initiatives within pharmaceutical companies that aim at a more efficient use of RWE pre-launch. Prof. Abrams will moderate the workshop and facilitate participant discussion of both the three topics presented, and their own experiences of using RWE in a HTA context.

HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

W20: HOW TO BRING PRO DATA INTO PAYER DECISION MAKING: PRO STRATEGIES IN PHARMACEUTICAL DEVELOPMENT

Brown 3 (L2)

Discussion Leaders: Ari Gnanasakthy, PhD, Head, Patient-Reported Outcomes, RTI Health Solutions, Research Triangle Park, NC, USA; Lynda Doward, MRes, European Head, Patient Reported Outcomes, RTI Health Solutions, Manchester, UK; Vasudha Bal, MSc, MBA, Director, Patient Reported Outcomes, Worldwide Health Outcomes, Value & Access, Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; Frank-Ulrich Fricke, PhD, Professor of Health Economics, Georg-Simon-Ohm University of Applied Science, Nurnberg, Neumarkt, Germany

PURPOSE: Patient-reported outcomes (PROs) are an accepted and often actively solicited source of evidence in the evaluation and approval of pharmaceutical interventions based on their clinical efficacy. The evaluation of new pharmaceuticals for reimbursement and/or health technology assessment (HTA) involves developing recommendations, typically of greatest interest to payers, that incorporate both clinical information about a treatment’s effectiveness and economic information about a treatment’s value (e.g., National Institute for Health and Care Excellence (NICE)). There is growing recognition that the patient perspective is also an important component in HTA. Thus, it is to be expected that PROs will be increasingly included in HTAs and will influence market access and pricing. A multitude of endpoints and variations in how payers in different countries assess evidence makes it difficult to understand the value of PRO data in reimbursement decisions. Understanding how decision makers utilize these data is critical in the increasingly constrained global health economic climate. This workshop aims to discuss the challenges, current research, and potential solutions associated with bringing patient perspectives into the reimbursement and market access decision-making process.

DESCRIPTION: The workshop will begin by summarizing payer requirements for PRO data in different countries. Examples of reimbursement decisions that included PRO data will be presented. The discussion leaders in turn will introduce the challenges and opportunities currently faced within drug development in bringing the patient perspective into payer decision-making forums. Participants will be encouraged to share their experience on how they overcame the challenges when including PROs in clinical trials to satisfy the needs of the regulators as well as the payers.

CLINICAL OUTCOMES RESEARCH

W21: OPTIMISING THE CONSTRUCTION OF INDIRECT TREATMENT COMPARISONS TO REFLECT COUNTRY-SPECIFIC HTA REQUIREMENTS

Space 1 (L0)

Discussion Leaders: Craig I. Coleman, PharmD, Co-Director and Methods-Chief, University of Connecticut/Hartford Hospital Evidence-Based Practice Center, Hartford, CT, USA; Rachel Beckerman, PhD, Principal, Maple Health Group, New York, NY, USA; Marc Bardou, MD, PhD, Gastroenterologist, Centre Hospitalier Universitaire Le Bocage, Dijon, France; Mathias Flume, PhD, Head of Department, Medical Association of Westphalia-Lippe (KVWL), Dortmund, Germany

PURPOSE: The purpose of this workshop is to understand the rationale behind why manufacturers construct indirect treatment comparisons (ITCs) and mixed treatment comparisons (MTCs) for HTA submissions; to give an overview of the pros and cons of commonly employed ITC methodologies; and to survey payer ITC requirements to understand common barriers and best practices in designing these analyses.

DESCRIPTION: In any given therapeutic area, the standard of care may be evolving and complex, and is likely to differ market to market. As a result, the standard of care at the time an asset’s actively-controlled registrational trial is designed may no longer be relevant once the product actually launches. Further, there are situations where an actively-controlled trial may not be run at all - due to ethical reasons, for example. Despite these realities, payers are increasingly requiring not just actively-controlled data for HTA submissions – but actively-controlled data versus their very specific ‘appropriate’ choice of comparator(s), which can vary by country. In order to meet these requirements, then, manufacturers are therefore encouraged to construct ITCs and MTCs, which can potentially introduce bias and uncertainty into the interpretation of their clinical data. In this workshop, an overview of the different types of methodologies used to construct ITCs and MTCs and their typical applications will first be given. Specific perspectives of payers’ ITC and MTC requirements across different markets (Germany, France) will be discussed. Then, case-based examples of how ITCs and MTCs have been considered by payers across markets will be critically appraised. Participants will come away with an understanding of market-specific requirements for ITCs, common pitfalls encountered when constructing these analyses, and best practice to employ in order to overcome them.

ECONOMIC OUTCOMES RESEARCH

W22: HARNESING “BIG DATA” AND TAMING HIGH DIMENSIONAL DECISION PROBLEMS FOR ECONOMIC EVALUATION

Space 2 (L0)

Discussion Leaders: William H. Crown, PhD, Chief Scientific Officer, Optum Labs, Cambridge, MA, USA; Sarah Davis, MPH, Senior Lecturer in Health Economics, School of Health and Related Research (ScHARR), University of Sheffield, Sheffield, UK; Bethan Woods, MSc, Research Fellow, Centre for Health Economics, University of York, Heslington, York, UK; Miqdad Asaria, MSc, Research Fellow, Centre for Health Economics, University of York, Heslington, York, UK

PURPOSE: Recent discussions around “Big Data” have focused on the analysis of large data sets and the use of real world data for health care decision making broadly. In this workshop we focus this discussion on (i) how big data can be used to inform decision models for economic evaluation; and (ii) how decision models increasingly generate large data sets that need to be analysed in a way that is informative for decision makers.
The potential value of large linked administrative datasets to develop an underlying disease and cost model. We will discuss methods for extracting information relevant to decision models from this type of data and alternative methods for analysing and presenting information relating to large numbers of subgroups. A second case study in diabetes will discuss the challenges of estimating treatment effects for economic evaluation from large observational data sets, and how this may be made more robust by using linked data. A third case study in osteoporosis will illustrate how meta-modeling can be used to analyse large probabilistic sensitivity analysis datasets that are generated by patient-level simulation decision models. Meta-modeling was used to estimate incremental net monetary benefit for alternative treatment strategies as a function of patient-level fracture risk, based on two million simulations whilst averaging over both patient-level heterogeneity and parameter uncertainty. We will conclude the workshop with an open discussion of the relative merits of the techniques proposed and the potential for these techniques to influence decision modeling practice and health care decisions.

**W23:** ADDING VALUE TO EQ-5D-3L VALUATION STUDIES: TAKING STOCK / PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE

**Discussion Leaders:** Paul Kind, Professor, Centre for Health Economics, Management and Policy, HSE University, St Petersburg, Russia; Roisin Adams, PhD, Deputy Head, National Centre for Pharmacoeconomics, Dublin, Ireland; Ling-Hsiang Chuang, PhD, Research Consultant, Phamaris Europe, Rotterdam, The Netherlands; Luciana Scalone, PharmD, PhD, Head of Outcomes Research Unit, Research Centre on Public Health (CESP), University of Milan Bicocca, Monza, Italy

**PURPOSE:** To explore the extent of support for creative innovation in developing the methods used to value EQ-5D-3L health states. To provide access to alternative elicitation methods (ranking, VAS rating and Time Trade-Off). Respondents valued a sample set of 13 health states selected from a pool of 43 drawn from across the severity range. The question at issue today is whether this study design continues to be fit for purpose and what scope there is for modifications that could enhance the robustness of EQ-5D value estimates that are increasingly required for economic evaluation of healthcare interventions. The workshop is specifically designed to be interactive and to provide the maximum possibility for attendee participation. Four key areas of methodological concern will be addressed – health state selection, preference elicitation methods, the valuation of dead and states worse than dead, constructing estimation models. Speakers from different countries with direct experience of MVH protocol modifications will review the issues and identify questions for discussion within each topic area. It is expected that workshop attendees without prior experience of valuation studies will acquire familiarity with the complexities of an often overlooked area of scientific enquiry. Attendees with relevant research experience will be actively encouraged to share their views and expertise. At key points in the workshop there will be the opportunity to test the collective views of attendees through ad hoc polling.

**DESCRIPTION:** We will use a series of international examples to show how decision models can use and generate large data sets. We will present a case study in which four linked administrative data sets were used to inform a decision model of stable coronary artery disease (the CALIBER project). This work illustrates the potential value of large linked administrative datasets to develop an underlying disease and cost model. We will discuss methods for extracting information relevant to decision models from this type of data and alternative methods for analysing and presenting information relating to large numbers of subgroups. A second case study in diabetes will discuss the challenges of estimating treatment effects for economic evaluation from large observational data sets, and how this may be made more robust by using linked data. A third case study in osteoporosis will illustrate how meta-modeling can be used to analyse large probabilistic sensitivity analysis datasets that are generated by patient-level simulation decision models. Meta-modeling was used to estimate incremental net monetary benefit for alternative treatment strategies as a function of patient-level fracture risk, based on two million simulations whilst averaging over both patient-level heterogeneity and parameter uncertainty. We will conclude the workshop with an open discussion of the relative merits of the techniques proposed and the potential for these techniques to influence decision modeling practice and health care decisions.

**W24:** ARE ANTIMICROBIALS PAVING THE WAY FOR ALL PHARMACEUTICALS? – A WORKSHOP ON THE COMMERCIAL SUSTAINABILITY OF R&D

**Discussion Leaders:** Alistair Mcguire, PhD, Professor of Health Economics, London School of Economics, London, UK; Michael Drummond, MCom, DPhil, Professor of Health Economics, Centre for Health Economics, University of York, Haxlington, York, UK; Monique Martin, PharmD, MSC, MBA, Vice President & General Manager HEOR Europe, MAPI, Uxbridge, UK

**PURPOSE:** To discuss the sustainability of R&D in the pharmaceutical industry. The Review on Antimicrobial Resistance Report (May 2015), while recognizing that antibiotics are different in character from other pharmaceuticals, pursued an objective to make R&D in this area “commercially sustainable”. To do so they proposed establishing a global organization able to “commit lump-sum payments to successful drug developers”. This is an attempt to de-link the profitability of a pharmaceutical product from its volume of sales, eliminating the need for companies to enhance sales volumes to cover the fixed costs of R&D. This idea was supplemented by discussion of how to reduce drug development costs, improve the efficiency of research and reduce regulatory constraints. While recognizing the differential characteristics of antibiotics this workshop will take the Review on Antimicrobial Resistance as a staging point to consider whether there are general lessons to be applied to thinking about the funding of pharmaceutical R&D. The workshop will begin with an initial statement on the current levels of R&D expenditure, the returns to R&D in this sector and the problems associated with funding R&D in the pharmaceutical sector. The relationship between R&D funding and product price will then be considered. A review of alternative R&D and product pricing relationships will be outlined with a range of examples drawn from successful co-ordination activities across governments, companies and regulators will be discussed. Future potential developments will then be outlined as mechanisms for de-coupling R&D investment from sales volume targets and product price. Audience participation will be sought by means of a survey of likely regulators will be discussed. Future potential developments will then be outlined as mechanisms for de-coupling R&D investment from sales volume targets and product price. Audience participation will be sought by means of a survey of likely developments (on entry to the room) and results will be discussed during the workshop.

**DESCRIPTION:** The workshop will be organised into three presentations. First, the Review on Antimicrobial Resistance Report (May 2015), while recognizing the differential characteristics of antibiotics this workshop will take the Review on Antimicrobial Resistance as a staging point to consider whether there are general lessons to be applied to thinking about the funding of pharmaceutical R&D. The workshop will begin with an initial statement on the current levels of R&D expenditure, the returns to R&D in this sector and the problems associated with funding R&D in the pharmaceutical sector. The relationship between R&D funding and product price will then be considered. A review of alternative R&D and product pricing relationships will be outlined with a range of examples drawn from successful co-ordination activities across governments, companies and regulators will be discussed. Future potential developments will then be outlined as mechanisms for de-coupling R&D investment from sales volume targets and product price. Audience participation will be sought by means of a survey of likely developments (on entry to the room) and results will be discussed during the workshop.

**W25:** INCORPORATING EQUITY INTO HEALTH TECHNOLOGY ASSESSMENT: AN ILLUSTRATION AND CRITICAL REVIEW OF GOOD PRACTICE

**Discussion Leaders:** Kevin Marsh, PhD, Senior Research Scientist & EU Director of Modelling and Simulation, Evidera, London, UK; Vitaly V. Omelyanovskyi, MD, PhD, Director, Center of HTA, Moscow, Russia; Alec Morton, PhD, Professor, Management Science, University of Strathclyde, Glasgow, UK; Sumitra Sri Bhashyam, PhD, Research Associate III, Modelling and Simulation, Evidera, London, UK

**PURPOSE:** Previous ISPOR workshops have identified that equity considerations, such as burden of illness, have an important role in health technology assessment (HTA), and that multi-criteria decision analysis (MCDA) can be used to incorporate equity into HTA. However, this faces a number of practical obstacles, including the violation of the independence of criteria. Understanding these challenges and identifying potential solutions are not only the concern of health economics and outcomes research (HEOR), but have also had the attention of other areas of research, notably operational research. The objective of this workshop is to illustrate and critically review approaches available for incorporating equity into MCDA, and to provide recommendations on good practice.

**DESCRIPTION:** The workshop will be organised into three presentations. First, the Review on Antimicrobial Resistance Report (May 2015), while recognizing the differential characteristics of antibiotics this workshop will take the Review on Antimicrobial Resistance as a staging point to consider whether there are general lessons to be applied to thinking about the funding of pharmaceutical R&D. The workshop will begin with an initial statement on the current levels of R&D expenditure, the returns to R&D in this sector and the problems associated with funding R&D in the pharmaceutical sector. The relationship between R&D funding and product price will then be considered. A review of alternative R&D and product pricing relationships will be outlined with a range of examples drawn from successful co-ordination activities across governments, companies and regulators will be discussed. Future potential developments will then be outlined as mechanisms for de-coupling R&D investment from sales volume targets and product price. Audience participation will be sought by means of a survey of likely developments (on entry to the room) and results will be discussed during the workshop.
and operational research literature to identify techniques to incorporate equity into MCDA, their advantages and disadvantages. Alec Morton will provide a critical assessment of these techniques from the perspective of HTA, identifying which are relevant to HTA, whether they are technically robust and justifiable; their accessibility to stakeholders; and the resources required to implement them. Vitaly Omelyanovsky will present some of the possible issues for MCDA usage within the Russian healthcare environment and illustrate the incorporation of equity into MCDA using the case study of the pilot of a MCDA to value orphan drugs in Russia. The objective of the MCDA was to rank orphan drugs for central government investment. The presentation will report the criteria list, and the results of an online interview with decision makers to elicit criteria weights using the swing voting approach. The audience will be invited to participate and share their experiences of dealing with equity in MCDA and their thoughts on the most appropriate ways to do so.

**USE OF REAL WORLD DATA**

**W26: MAXIMIZING VALUE: REALIZING THE POTENTIAL OF ROUTINELY COLLECTED DATA**

**Space 2 (L2)**

**Discussion Leaders:** Heiner C. Bucher, MD, MPH, Professor, Department of Clinical Research, Basel Institute for Clinical Epidemiology & Biostatistics, Basel, Switzerland; Ed Mills, PhD, MSc, Director, Redwood Outcomes, Vancouver, BC, Canada; Christopher O’Regan, MSc, Head of Health Technology Assessment & Outcomes, Merck Sharp & Dohme Limited, Hertfordshire, UK

**Purpose:** To present and discuss innovative approaches for: 1) the use of routinely collected claim data for large scale health care interventions by pragmatic trial design and 2) for system wide resource studies by privacy preserving data mining using probability-based data linkage of claim data with clinical cohort studies. We will use examples from settings representing both the developed and developing world.

**Description:** Routinely collected data are traditionally used in phase IV decision-making, mainly for comparative effectiveness and safety studies. Routinely collected drug use data of high quality and density, however, can be also used for intervention trials. We show examples of pragmatic intervention trials to optimize drug use in different indications. Interventions can be done at the health system level to monitor drug prescribing, to promote more appropriate drug prescribing and to benchmark individual physicians against their peers. Resource use of data in health economic analyses for a given patient population and setting is often lacking and has to be derived from different types of information. Privacy preserving data mining using probability-based linkage of claim data with cohort study data can overcome these limitations. We show and discuss the challenge of our data linkage approach and illustrate its relevance for the generation of high quality evidence using examples from HIV infection and hepatitis C. Heiner C. Bucher and Ed Mills will share their experience in comparative effectiveness research using large cohort studies and pragmatic trials in national and international networks. Chris O’Regan will moderate the session and stimulate the discussion on innovative approaches to better use of routinely collected data.

**ECONOMIC OUTCOMES RESEARCH**

**W27: ASSESSING THE SOCIETAL, HEALTH CARE, AND PATIENT IMPACT OF LARGE HEALTHCARE INNOVATION PARTNERSHIPS USING HEALTH ECONOMIC MODELING METHODS: LESSONS FROM THE EUROPEAN INNOVATION PARTNERSHIP ON ACTIVE AND HEALTHY AGEING (EIP ON AHA)**

**Space 2 (L2)**

**Discussion Leaders:** Christian Ernst Heinrich Boehler, PhD, MSc, Scientific Officer, Joint Research Centre (JRC), Institute for Prospective Technological Studies (IPTS), European Commission, Seville, Spain; Lotte Steuten, PhD, Associate Professor, Fred Hutchinson Cancer Research Center, University of Washington and Panaxela bv, Seattle, WA, USA; Leandro Pecchia, PhD, MSc, Assistant Professor, School of Engineering, University of Warwick, Coventry, UK; Mirjam Vollenbroek, PhD, Professor, Faculty of Electrical Engineering, Mathematics and Computer Science, University of Twente and Roessingh Research and Development (RRD), Enschede, The Netherlands

**Purpose:** On European and national levels substantial efforts have gone into setting up partnerships that aim to stimulate the development and implementation of healthcare innovations. This workshop will identify challenges with and novel solutions for monitoring and assessing the societal, healthcare and patient impact of such partnerships based on the experiences from the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA).

**Description:** Monitoring and assessing the societal, healthcare and patient impact of large innovation partnerships is challenging for many reasons, including 1) the wide range of interventions developed; 2) the variety in target populations; 3) the need for fast, iterative assessments of technologies from development to implementation stages; 4) the need for ready available repositories of (country-specific) epidemiology and cost data; and 5) the need to extrapolate results over time and across different settings. Dr. Boehler will introduce the topic and discuss the rationale for, and challenges associated with, assessing the health and economic outcomes of large innovation partnerships in the context of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA). Dr. Steuten will discuss the use of iterative health economic modelling and present an online tool based on a highly adaptable Markov model that allows stakeholders of the EIP on AHA to estimate the health economic impact of their interventions in real-time. Two case studies will be presented to illustrate this novel approach: one on the cost-effectiveness of a planned device to predict falls in the elderly, and another one to assess the cost-effectiveness of mobile monitoring and training to tackle frailty. Participants in the workshop will be invited to answer a survey asking for their views on methods to assess the impact of large-scale innovation partnerships and all will be encouraged to share their experience and views during the workshop.

**PATIENT-REPORTED OUTCOMES & PATIENT PREFERENCE RESEARCH**

**W28: SECONDARY ANALYSIS OF QUALITATIVE DATA TO INFORM THE DEVELOPMENT OF PRO INSTRUMENTS**

**Space 2 (L2)**

**Discussion Leaders:** Monica Hadi, PhD, Research Manager, Patient-Centred Outcomes, Mapi Group, London, UK; Paul Swinburn, MRes, Research Director, Patient-Centered Outcomes, Mapi Group, London, UK; Elizabeth Gibbons, MSc, Senior Research Scientist, Health Services Research Unit, University of Oxford, Oxford, UK

**Purpose:** This workshop will demonstrate the use of secondary analysis of qualitative data for the development of PRO instruments. The session will provide an overview of the technique and methodological underpinnings, its application to different types of data, and its use in the analysis of existing qualitative data for the development of new PRO instruments.

**Description:** The FDA recognises the use of qualitative interviews with patients as an important step in the development of a new PRO instrument. Secondary analysis of qualitative interviews allows for an independent investigation of a new research question, different from the intentions pursued in the primary study. This is a useful technique which allows for the use of existing data whilst preserving valuable patient input. This session will be presented in 3 steps. The first section will cover the underpinnings of secondary analysis and its application, particularly for the development of PROs. The second section will involve the demonstration of secondary analysis on existing patient and clinician interviews to derive themes for a new PRO. At this stage, the audience will be invited to think of a new research question and, with the use secondary analysis techniques on interview transcripts, generate codes and themes to be used in the development of a new PRO. The final section will discuss the challenges faced by this approach as well as the more general benefits for development of PRO instruments. Audience participation in discussions and workshop will be encouraged throughout the session.
HEALTH POLICY DEVELOPMENT USING OUTCOMES RESEARCH

W29: HOW SHOULD WE BE RESPONDING TO CONDITIONAL APPROVALS FROM HTA BODIES?
Brown 3 (L2)
Discussion Leaders: Mondher Toumi, MD, MSc, PhD, Professor of Public Health, Department of Public Health, Aix-Marseille University, Marseilles, France; Alan A. Martin, MSc, Director, Value Evidence Analytics, Research and Development, GlaxoSmithKline, Uxbridge, UK; Yumi Asukai, MSc, Director Value Evidence Analytics, Research and Development, GlaxoSmithKline, Uxbridge, UK
PURPOSE: This workshop will discuss different real-world evidence options available to respond to conditional reimbursement decisions that require further evidence generation. We will review the pros and cons associated with each option as well as explore how and whether economic models continue to have a role in the post-launch space in the face of empirical evidence. DESCRIPTION: Economic models are often the cornerstone of value demonstration of a new product at time of launch. However, data on actual use in the real-world is necessarily limited for a new product and conditional reimbursement is becoming increasingly common. The debate on real-world data has dominated many discussion forums from a payer perspective. Here, we discuss the pros and cons of two main types of real-world research, specifically in the context of responding to payer queries. We will also explore how these types of data fit back into the original economic model; or, whether it is necessary to revert back to modelling at all when real-world evidence is available. Mondher Toumi will review prospective and retrospective observational studies in the context of responding to likely questions from reimbursement authorities; he will also highlight weaknesses of observational studies and suggest how these issues can be addressed. Alan Martin will discuss when pragmatic trials are the evidence of choice, and can overcome limitations of observational studies as seen by reimbursement bodies. Yumi Asukai will discuss which data type best fits into the modelling framework when refining the original economic model. Additionally, she will discuss whether the totality of the evidence collected could mean that modelling be abandoned in favour of ‘empirical evaluation’ when responding to HTA bodies’ request for further value demonstration. Comment and discussion will be sought by all three discussion leaders, on the issues and suggested remedies.

USE OF REAL WORLD DATA

W30: MANAGING THE EFFECTS OF CHANNELING IN RELATIVE EFFECTIVENESS STUDIES OF NEWLY LAUNCHED MEDICATIONS
Space 1 (L0)
Discussion Leaders: Jessica Jalbert, PhD, Director of Pharmacoepidemiology, LASER Analytica, New York, NY, USA; Christiane Gasse, PhD, Senior Researcher, Aarhus Universitet, Aarhus, Denmark; Tjeerd Van Staa, MD, PhD; Professor of Health Research, Farr Institute of Health Informatics Research, University of Manchester, Manchester, UK; Billy Amzal, PhD, Global Scientific Vice President, LASER Analytica, London, UK
PURPOSE: The goal of relative effectiveness (RE) is to inform decision-making by stakeholders in the healthcare system by comparing healthcare interventions in routine clinical practice. Secondary data sources such as administrative claims data are widely used for RE studies and while they can be a source of longitudinal, comprehensive information on drug dispensations and healthcare encounters, they often lack detailed clinical data. This may be particularly problematic in RE studies of newly launched medications, as newer medications may be selectively prescribed to patients for the same indication but with more severe disease, with expectations of increased effectiveness or better tolerability. As many post-marketing commitments are initiated shortly after launch, findings from RE studies may be biased against the newly launched medication if the potential for channeling is ignored. The purpose of this workshop is to explain how channeling may arise and to present ways of detecting, quantifying, and mitigating the effects of channeling. Mondher Toumi will then discuss the types of RE studies that may be particularly prone to the effects of channeling, using recent or ongoing post-marking RE studies as case examples. DESCRIPTION: The workshop will consist of three 15-minute presentations. First, Dr. Gasse will demonstrate how and under what circumstances channeling may arise in the context of RE studies of newly launched medications. Dr. Jalbert will then discuss the types of RE studies that may be particularly prone to the effects of channeling, using methods that can be used to detect channeling, including stratification and propensity score modelling. Dr. Amzal will then demonstrate statistical modelling options and discuss data requirements needed to quantify the effects of channeling. These presentations will be followed by an interactive panel discussion moderated by Dr. Van Staa during which the audience will be encouraged to ask questions and share their experiences as well as approaches to detecting, quantifying, and mitigating the effects of channeling in RE studies of newly launched medications.

CLINICAL OUTCOMES RESEARCH

W31: NETWORK META ANALYSIS MODELS FOR DOSE-RESPONSE AND CLASS EFFECTS IN DECISION MAKING
Brown 2 (L2)
Discussion Leaders: Rhiannon Kate Owen, MSc, Research Associate/NIHR Doctoral Research Fellow, Department of Health Sciences, University of Leicester, Leicester, UK; Kristian Thorlund, PhD, MStat, Director, Redwood Outcomes, Vancouver, BC, Canada; David Mawdsley, PhD, Research Associate, School of Social and Community Medicine, University of Bristol, Bristol, UK; Timothy Reason, MSc, Senior Consultant, Real-World Evidence Solutions, IMS Health, London, UK
PURPOSE: This workshop presents recently proposed models to incorporate dose-response and class effects in network meta-analysis and to discuss the interpretation of the results and implications for decision making. DESCRIPTION: Network Meta-Analysis (NMA) allows the synthesis of relative treatment effects from randomised controlled trials that form a connected network of treatment comparisons. A common challenge in NMA is how to deal with multiple doses, treatments and classes that are available for a given indication. There is usually a choice between ‘grouping’ vs ‘splitting’ treatments reflecting a trade-off between precision and generalisability. Recently, several statistical methods have been proposed to incorporate dose and class effects in NMA. In this workshop we describe these different approaches, and end with a discussion of how to interpret the results and the implications for decision making. Rhiannon Owen will show how to fit hierarchical models where treatment effects at the ‘dose’, ‘agent’ and ‘class’ level are modelled simultaneously within a multi-level structure, including models that incorporate dose-response constraints. Kristian Thorlund will show how to model dose-response explicitly as a covariate, including how to model dose-related effects as a fraction of the minimally therapeutic dose. David Mawdsley will show how to fit models where richer dose-response profiles such as those seen in Emax models can be parameterised. Finally Tim Reason will lead a discussion of the advantages and disadvantages of the different methods and their interpretation for decision making. We will end the session by asking the audience for questions and feedback to facilitate an open discussion of the methods presented in the workshop.

ECONOMIC OUTCOMES RESEARCH

W32: HOW TO COMBINE OPEN ACCESS ARTICLES AND OPEN ACCESS ECONOMIC EVALUATION MODELS IN HEALTH CARE PROGRAMMES: REAL TIME UPDATING AND LOCAL CUSTOMIZATION OF PUBLISHED ECONOMIC MODELS
Space 2 (L0)
Discussion Leaders: Giorgio L. Colombo, MSc, Professor Department of Drug Sciences, School of Pharmacy, University of Pavia, Milan, Italy; Sandra Le, PhD, Editorial Development Manager, Dove Medical Press Limited, Macclesfield, England; Stefano Govoni, Pharmacologist & Professor Department of Drug Sciences, School of Pharmacy, University of Pavia, Milan, Italy
PURPOSE: Economic models need to be constantly updated. The aim of this workshop is to provide new tools to combine the analysis of research articles with a web-based model through the Open Access System publication. DESCRIPTION: Models in economic evaluation of health care programmes extrapolate the comparative trial data and epidemiologic data to a patient lifetime horizon by using literature-derived estimates and different scenarios of treatment outcomes, to identify the utility value of each health state, the probabilities of
transition among health states, resource use, and costs. Over time these economic models need to be constantly updated on cost data to ensure a valid comparison between the different countries in which the analysis has been conducted. The Open Access System’s primary aim is to disseminate the results of the project in its scholarly journals. In this workshop, we will show a practical framework which combines the analysis, the publication, and the updating of the data through a web-based platform. Based on our experience, the contributors will involve short presentations about:

1) Introduction to dynamic economic model of simulation
2) How an Open Access System works from publication to the customization of the models
3) How data work in the model

a) Enter all the data across European countries
b) Customize and change the parameters on the base of the different countries
c) Compare data and create a benchmark database of the outcomes
4) How different data can be modified and how the model can be adapted in real-time

Audience participants will be encouraged to try different simulations on models and their application. This workshop is suitable for health economic modelers, individuals responsible for health outcomes and health economic strategies, payers, and other decision makers.

W33: UNCERTAINTY OF UNCERTAINTY ESTIMATES IN ECONOMIC MODELLING OF ONCOLOGY

Brown 1 (L2)

Discussion Leaders: T Lanitis, MSc, Senior Research Associate, Evidera, London, UK; Zoltán Kaló, PhD, Professor of Health Economics, Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary; Noemi Muszbek, MSc, Senior Research Scientist, Evidera, London, UK

PURPOSE: In oncology, the role of biomarkers and personalized medicine is rising, as are pressures for early access, resulting in adaptive pathways. Patient populations are therefore increasingly fragmented, whilst timelines for evidence generation are shortened. Consequently, uncertainty is becoming a key factor in reimbursement decisions. Assessment of uncertainty tends to focus on parameter uncertainty using probabilistic sensitivity analysis (PSA). However, PSA can be based on conventions and convenience, with the results often representing assumptions of the uncertainty, rather than uncertainty in the assumptions adopted in the model. The purpose of this workshop is to highlight, discuss the current approaches and underlying assumptions used in PSA and illustrate their effect on results contrasting them to current guidelines. How the uncertainty assessment should be used in decision making will be discussed with the audience.

DESCRIPTION: The discussion leaders will highlight the scope, methods, presentation of results used in current practice of PSA based on a recent review of NICE technology appraisals. These will be contrasted with guidelines, highlighting the underlying implicit assumptions. To demonstrate the impact of alternative methodological approaches and assumptions, a case-study using a 3-state cohort Markov model in advanced oncology will be presented. Implicit assumptions underlying commonly used methods regarding distributions, correlations, variations, and structural choices will be drawn out and examined in terms of their face validity and impact on results. The presentations will conclude with an illustration of how uncertainty is taken into account in decision making, the role parameter uncertainty plays and scenarios in which such results are of major significance. The changing role of uncertainty in the decision making and the limitations and interpretation of PSA will be discussed with the audience.
FORUMS

ISPOR FORUMS – SESSION I: MONDAY, 9 NOVEMBER: 18:15-19:15

F1: RARE DISEASE CLINICAL TRIALS: EMERGING GOOD PRACTICES FOR CLINICAL OUTCOMES ASSESSMENT OUTCOMES (PROS, CLINROS & OBSROS) MEASUREMENT

Gold (L2)
Moderator: Margaret K. Vernon, PhD, Senior Research Scientist, Evidera, London, UK
Speakers: Donald L. Patrick, PhD, MSPH, Professor, Department of Health Services and Director, Seattle Quality of Life Group and Biobehavioral Cancer Prevention and Training Program, University of Washington, Seattle, WA, USA; Eleanor M. Perfetto, PhD, MS, Professor, Pharmaceutical Health Services Research, University of Maryland, Baltimore, MD, USA and Senior Vice President, Strategic Initiatives, National Health Council, Washington, DC, USA

DESCRIPTION: There are significant challenges to developing, modifying and selecting PRO, ClinRO and ObsRO measures for rare disease treatment evaluation. Conformance to regulatory guidance for the evaluation and proof of treatment benefit using these types of endpoints is taken into account in terms of how these measures and methods can be developed or adapted. The authors draw on the clinical outcomes assessment (COA) framework and use specific examples to discuss the potential obstacles involved in implementing or developing PRO, ClinRO or ObsRO endpoints for RD studies. They will present possible solutions to address common challenges that arise when working with RD populations, emphasizing pragmatic approaches to these challenges.

Presented by ISPOR COA Measurement in Rare Disease Clinical Trials – Emerging Good Practices Task Force

F2: MAPPING TO ESTIMATE UTILITY VALUES FOR COST PER QALY ECONOMIC ANALYSIS - GOOD RESEARCH PRACTICES

Brown 3 (L2)
Moderator/Speaker: Allan J Wailoo, PhD, Professor of Health Economics, SchARR, University of Sheffield and Director, NICE Decision Support Unit, Sheffield, UK
Speaker: Joshua Ray, MSc, Head of Health Economics Modelling, F. Hoffmann-La Roche, Basel, Switzerland

DESCRIPTION: “Mapping” is the practice of estimating health utilities from other patient reported outcome measures and/or clinical indicators. It is commonly undertaken to link evidence from clinical studies to QALY based economic evaluations. This forum will operate as a workshop guided by issues raised in the “Use of Mapping to Estimate Utility Values from Non-Preference Based Outcomes Measures for Cost per QALY Economic Analysis Good Research Practices Task Force”. Members of the Task Force will provide brief presentations on the issues and recommendations proposed as a framework for audience-led discussion. The forum will describe those situations where mapping is/is not appropriate, and outline pre-statistical modelling considerations regarding data and links to the economic evaluation. Discussions will then cover the selection of model types and specifications, reporting standards, and how to use results in model based and clinical trial based economic evaluations. The forum will provide an opportunity to improve current practice both for the conduct of modelling studies and the use of the results in economic evaluation.

Presented by the Mapping to Estimate Health State Utility Values from Non-Preference Based Outcomes Measures for Cost per QALY Economic Analysis Good Research Practices Task Force

F3: MEDICAL NUTRITION – TERMS, DEFINITIONS, REGULATIONS & EMERGING GOOD PRACTICES FOR ECONOMIC EVALUATION

Brown 1-2 (L2)
Moderator: Karen Freyer, PhD, Nutritionist & Nutrition Economist, School for Public Health and Primary Care (CAPHR), Maastricht University, Zoetermeer, The Netherlands
Speakers: Sheri Volger, MS, Principal Clinical Scientist, Nestlé Nutrition R&D, King of Prussia, PA, USA; Oznur Seyhun, MSc, MFE, Senior Market Access Manager, Abbott Nutrition, Istanbul, Turkey; Josephine Maukspof, PhD, Vice President, Health Economics, RTI Health Solutions, Research Triangle Park, NC, USA

DESCRIPTION: Medical nutrition comprises parenteral nutrition (regulated in pharmaceutical legislation), as well as all forms of enteral nutrition support that are regulated as “foods for special medical purposes” (FSMP), as defined by the European Commission Directive 1999/21/EC, independent of the route of application. Medical nutrition outcomes research includes clinical, economic, and health-related quality of life outcomes to assess the impact of medical nutrition products on patient health and disease. Evidence on the use of medical nutrition for patients suffering from disease-related malnutrition (DRM) has demonstrated functional, as well as clinical, benefits. Nevertheless, evidence of the integral role of nutrition in disease progression, as well the onset and evolution of lifestyle-related disorders, has forced health care decision makers to realize the importance and impact of medical nutrition products. Presenters will discuss their work to date on definitions and regulations for medical nutrition for adult patients undergoing metabolic stress for a variety of reasons: disease, fasting, surgery, trauma, etc.


F4: HEALTH TECHNOLOGIES PRICING AND DECISION MAKING IN THE CENTRAL SOUTH EUROPE: WHAT, WHERE, WHEN, AND HOW?

Space 2 (L0)
Moderator: Tomas Dolezal, MD, PhD, President, ISPOR Czech Chapter and Director, IHETA, Prague, Czech Republic
Speakers: Malwina Holownia, MPharm, Director of Economics, Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia; Mary Geitona, MSc, PhD, Professor, University of Peloponessie, Athens, Greece; Bertalan Nemeth, MSc, Senior Health Economist, Syreon Research Institute, Budapest, Hungary; Pero Draganic, MD, PhD, Assistant Professor, Principal Advisor for Safe Use of Medicines, HALMED, Croatian Agency for Medicinal Products and Medical Devices, Zagreb, Croatia

DESCRIPTION: Health technology has enormous potential to change our understanding of the disease, reform the delivery of health care services and improve population outcomes. However, it does come at a price that needs to be reimbursed from the public budget. With the development and perceived importance of health technology assessment (HTA) processes in the CEE countries many attempts have been made to further pressure innovative health technology pricing by utilizing HTA. This Forum will raise and discuss the issues of pricing of innovative health technologies. CEE countries fall into the category of middle-income countries with large public health care system and very low budget. The presenters will further address the issues of pricing with examples of how they can be solved and how they are currently dealt with.

Presented by the ISPOR CEE Network

Strengthening health care systems and building health care resources in the Central & Eastern Europe (CEE) region is the core focus of the ISPOR CEE Network. For more information on the ISPOR CEE Network and to get involved: visit www.ispor.org >> Regional Chapters/Networks >> ISPOR Networks Index >> ISPOR Central & Eastern Europe Network
F5: PARALLEL TRADE: CAN WE CURB THE IMPACT ON CENTRAL & EASTERN EUROPEAN (CEE) COUNTRIES?
**Space 1 (L0)**
**Moderator:** Joanna Lis, PhD, President, ISPOR Poland Chapter, Adjunct Professor, Pharmacoeconomics Department, Medical University of Warsaw, and Director, Market Access, Sanofi, Warsaw, Poland
**Speakers:** Zoran Stejcev, PharmD, PhD, Assistant Professor, Faculty of Pharmacy, UKIM-Skopje, Skopje, Macedonia; Jana Skoupa, MD, MBA, Researcher, Charles University, Prague, Czech Republic; Natalia Bogavac-Stanojevic, PhD, Assistant Professor, Faculty of Pharmacy, University of Belgrade, Belgrade, Serbia; Assena Stoimenova, PhD, Associate Professor and Executive Director, The Bulgarian Drug Agency, Sofia, Bulgaria

**DESCRIPTION:** With the formation of the European Community (EU), common market gave birth to the EU parallel trade. Early theories of market integration through parallel trade gave full boost to profiting by purchasing a product at a lower price in one country and reselling it at a higher cost. However, the economic reality is very different, when it comes to pharmaceutical products. Namely, over the last five years, trend has intensified to the point where a patient in a CEE country goes to fill a prescription and the medication is not available anywhere in the country. As the parallel importers have exponentially increased the volumes, the pharma companies are trying to curb this abuse, by attempting to provide readily available supplies for the patients in each country, based on previous purchase trends. This Forum will raise and discuss the issues surrounding this phenomenon and will seek best practices on how to curb this impact.

**Presented by the ISPOR CEE Network**

F6: BUDGET RESTRICTIONS FOLLOWING THE ECONOMIC CRISIS: THREATS OR OPPORTUNITIES FOR THE DEVELOPMENT OF ECONOMIC EVALUATION IN THE SOUTHERN EUROPEAN REGION
**Space 3 (L0)**
**Moderator:** Lorenzo Mantovani, DSc, President, ISPOR Italy-Milan Chapter and Associate Professor of Public Health, Research Centre on Public Health (CESP), University of Milano-Bicocca, Monza, Italy
**Speakers:** Carlos Gouveia Pinto, PhD, President, ISPOR Portugal Chapter and President, Research Center on the Portuguese Economy (CISEP), School of Economics & Management, University of Lisbon, Lisbon, Portugal; Carme Pinyol, MD, MSc, Founder & Director, INNOVA -Strategic Consulting, Barcelona, Spain; Americo Cicchetti, DSc, Professor of Management and Healthcare Management & Director, Graduate School of Health Economics and Management, Catholic University of Sacred Heart (ALTEMS), Rome, Italy; John Vlantopoulos, PhD, President, ISPOR Greece Chapter and Professor of Health Economics, School of Economics and Political Science, University of Athens, Athens, Greece

**DESCRIPTION:** The Forum will discuss the ways in which the economic crisis has affected Southern European countries and its impact on health care budgets. This shall provide the framework to analyze changes that occurred (or not) in the economic evaluation of pharmaceuticals in Greece, Italy, Portugal and Spain.

**Presented by ISPOR Regional Chapters in Greece, Italy-Milan, Italy-Rome, Portugal, and Spain**

F7: CONJOINT ANALYSIS: GOOD RESEARCH PRACTICES FOR STATISTICAL ANALYSIS
**Brown 2 (L2)**
**Moderator:** A. Brett Hauber, PhD, Senior Economist & Vice President, Health Technology Assessment (HTA), RTI Health Solutions, Research Triangle Park, NC, USA
**Speakers:** Maarten J. Uzerman, PhD, Professor of Clinical Epidemiology & Health Technology Assessment (HTA) and Head, Department of Health Technology & Services Research, University of Twente, Enschede, The Netherlands; John F.P. Bridges, PhD, Associate Professor, Department of Health Policy and Management and International Health, John Hopkins Bloomberg School of Public Health, Baltimore, MD, USA; Karin G. M. Groothuis-Oudshoorn, PhD, Assistant Professor, Health Technology and Services Research, University of Twente, Enschede, The Netherlands

**DESCRIPTION:** The forum will discuss the task force’s final recommendations on the appropriate use and limitations of statistical methods for analyzing data from conjoint-analysis studies. The range of options for estimating data from discrete-choice experiments, including simple-sum approaches, generalized linear methods, conditional logit, random-parameters logit, hierarchical Bayes, and latent-class analysis will be discussed. The goal of this task force is to provide researchers with an understanding of the implicit and explicit assumptions required to apply different analysis methods to conjoint analysis data. Finally, we will make recommendations for day-to-day use. It will help researchers and reviewers judge the appropriateness of different statistical methods for a given choice problem and evaluate the strengths and limitations of conjoint-analysis studies.

**Presented by the ISPOR Conjoint Analysis Good Research Practices Task Force**

F8: PATIENT ENGAGEMENT: WHAT IS IN A NAME?
**Brown 1-2 (L2)**
**Moderator:** Todd Berner, MD, Medical Director, Head Global Medical Affairs Strategy, Immunology, Baxalta, Inc., Bannockburn, IL, USA
**Speakers:** Eleanor M Perfetto, PhD, MS, Professor, Pharmaceutical Health Services Research, University of Maryland, School of Pharmacy, and Senior Vice President, Strategic Initiatives, National Health Council, Washington, MD, USA; Russell Wheeler, Patient Advocate, Leber’s Hereditary Optic Neuropathy, Winchester, UK

**DESCRIPTION:** The latest buzz words in health care start with “patient”. There is patient centered, patient focused, patient engagement, and patient driven. These terms are often followed by drug development, preference, or outcomes research. But, what is meant by these terms and more importantly, do differences in its meaning, use, and interpretation matter? This forum will discuss these terms, various definitions used by different stakeholders, and explore the importance of understanding the context and usage, as well as the need for standardization.

**Presented by the Patient Engagement in Research Working Group**

F9: MULTI-CRITERIA DECISION MAKING IN THE CENTRAL & EASTERN EUROPEAN (CEE) REGION: ARE WE THERE YET?
**Space 2 (L0)**
**Moderator:** Zoltán Kaló, PhD, Professor of Health Economics, Department of Health Policy and Economics, Faculty of Social Sciences, Eötvös Loránd University, Budapest, Hungary
**Speakers:** Rok Hren, PhD, MSc, IHF (HE), President, ISPOR Slovenia Chapter and Assistant Professor, University of Ljubljana, Ljubljana, Slovenia; Vitaly Omelyanovskiy, MD, PhD, DSc, President, ISPOR Russia HTA Chapter and Director, Center for Health Technology Assessment, Russian Presidential Academy of National Economy and Public Administration, Center of Comprehensive Health Technology Assessment, Ministry of Health of the Russian Federation, Moscow, Russia; Maciej Niwada, MD, PhD, MA, CEO, HealthQuest and Professor, Department of Clinical & Experimental Pharmacology of Medical University of Warsaw, Warsaw, Poland; Oresta Piniazhko, MSPharm, PhD student, Danylo Halychsky Lviv National Medical University, Lviv, Ukraine
DESCRIPTION: During the last 12 months, MCDM has been introduced to many decision makers in the CEE region. However, true implementation of MCDM requires full involvement of all stakeholders, which so far have never been utilized in the decision making process. Hence, the implementation of MCDM has been somewhat delayed, as there appears to be a need for training and standards relating to the introduction of MCDM. This Forum will discuss different MCDM initiatives and approaches in the CEE region. Presenters will address best practices and implementation steps that work in the middle-income countries. Audience interaction is anticipated. 
Presented by the ISPOR CEE Network

F10: MARKET ACCESS PRICING IN CENTRAL & EASTERN EUROPE (CEE)
PRACTICAL GUIDE TO SUCCESSFUL REIMBURSEMENT
Space 1 (L0)
Moderator: Olha Zaliska, PhD, DSci (Pharm), President, ISPOR Ukraine Chapter and Professor, Danylo Halychsky Lviv National Medical University, Lviv, Ukraine
Speakers: Alexey Kurylev, MD, Assistant, Department of Clinical Pharmacology and Evidence-based Medicine, First Pavlov State Medical University of St. Petersburg, Saint Petersburg, Russia; Tarik Catic, MScPharm, PhD(s), Researcher and President, ISPOR Bosnia and Herzegovina Chapter, Sarajevo, Bosnia; Yalcin Kaya, MD, Public Health Specialist & Senior Manager, Market Access, Public Affairs and Corporate Affairs, Bristol-Myers Squibb, Istanbul, Turkey; Marian Sorin Paveliu, PhD, MD, Associate Professor, Pharmacology, Titu Maiorescu University, Bucharest, Romania

DESCRIPTION: Market access pricing is fundamental to the process of reimbursement in CEE region. With financial optimization of the healthcare systems, there is a growing need for the definition of the right approaches to market access that are mutually acceptable to payers and pharmaceutical industry. Patients are neglected in the process, even though the healthcare system is funded by taxation process. The transparency of the decision-making process and market access pricing is under a veil of secrecy. This Forum will raise and discuss issues surrounding market access pricing and how to achieve mutual agreement on both sides of the fence that will result in optimized and better treatment options for patients. During this audience interactive forum, the presenters will provide successful market access pricing and reimbursement examples.
Presented by the ISPOR CEE Network

ISPOR FORUMS – SESSION II: TUESDAY, 10 NOVEMBER: 17:45-18:45 CONTINUED

Value in Health Regional Issues focusing on Central & Eastern Europe, Western Asia, and Africa (CEEWAA)

Value in Health Regional Issues, launched in 2012, is a scientific online regional journal encouraging and enhancing the science of pharmacoeconomics/health economics and health outcomes research and its use in health care decisions in Asia, Latin America, Central & Eastern Europe, Western Asia, and Africa (CEEWAA). Value in Health Regional Issues (CEEWAA) provides publication opportunities to researchers, practitioners and policy-makers and shares pharmaceutical and medical device outcomes research results from the CEEWAA regions.

Manuscript submission is year-long. To be considered for Volume 10 October 2016, please submit your manuscript by February 15, 2016.

Topics:
Value in Health Regional Issues considers articles on health care policy analysis, outcomes research (clinical, economic, and patient-reported), empirical studies, methodological studies, and articles on health care resources in CEEWAA.

Health care decision-maker commentaries that stimulate communication between health outcomes researchers and policy-makers are welcome. Commentaries are expected to include discussion on how researchers can better respond to the needs of those making clinical and financial decisions in health care.

Criteria:
• One of the authors of an article should reside in CEEWAA and
• Empirical study articles should include subjects from population(s) in CEEWAA.

Manuscript Submission:
The Value in Health Regional Issues (CEEWAA) articles are published online after acceptance.
To submit a manuscript, please go to http://www.ispor.org/publications/ViHRI/index.asp.
CHALLENGES AND OPPORTUNITIES IN HEART FAILURE: UNMET CLINICAL NEEDS, ECONOMIC BURDEN, AND IMPACT ON SOCIETY

Heart failure is a progressive, debilitating disease that affects more than 21 million in US and Europe alone. It has a mortality rate of more than 50% within 5 years of diagnosis, and this has a significant impact on patients, families, health care systems, and the society at large.

This educational symposium will be focused around a series of lively discussions addressing the challenges we face in heart failure treatment and the possibilities for future therapy, as well as heart failure’s societal and economic effects. The symposium will include a presentation on the current challenges in the clinical management of heart failure patients who have concomitant conditions, particularly those with diabetes, hypertension, anaemia, and renal impairment. A second presentation will address heart failure’s impact on society and its economic burden, in the context of health economics and healthcare policy. The symposium will then focus on country-specific case presentations on the economic and societal impacts of heart failure, to bring its implications to life.

Moderator:
Lorenzo G. Mantovani, Associate Professor of Public Health, Center for Public Health Research, Università degli Studi di Milano-Bicocca, Milan, Italy

Speakers:
Joe Gallagher, Clinical Lecturer in Medicine, University College Dublin, Dublin, Ireland
Javier Mar Medina, Chief of the Health Management Unit, Hospital Alto Deba, Mondragón, Spain

SUNDAY, 8 NOVEMBER | 17:30-18:30 | Brown 3 (L2)

BIG DATA, QUICK DATA OR DEEP DATA? INNOVATIVE DESIGNS FOR REAL-WORLD EVIDENCE GENERATION

As real-world data generation has become a critical element for decision making and evaluation of drugs throughout lifecycle, the collection of relevant data in due time remains a challenge. Large observational studies are not always feasible nor meeting the shorter timing of evaluation, especially at drug launch. Health care databases, when existing, are known to have numerous caveats and gaps. Market research data are often not considered adequate for agencies’ decisions.

The objective of this Symposium is to introduce innovative real-world study concepts or designs to bridge those gaps and offer adequate real world data in sufficiently short time to meet the regulatory and health technology assessment (HTA) requirements.

Such approaches will be illustrated by real cases, and viewpoints from high-level scientific experts, industry, and public health decision makers will be presented.

Moderator:
Lucien Abenhaim, MD, PhD, Chairman, LASER Analytica, London, UK

Speakers:
Billy Amzal, X-Eng, MSc, MPA, PhD, Global Scientific Vice President, Consulting & Analytics & Global Head, Decision Analytics, LASER Analytica, London, UK & Paris, France
Lamiae Grimaldi, PharmD, MSc, PhD, Executive & Scientific Vice President, Real World Research, Laser Analytica, and Associate Professor of Epidemiology, CNAM, Paris, France
Michael Seewald, PhD, Global Head Real World Evidence, Novartis, Basel, Switzerland

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INNOVATIVE PRICING & THE RELATIONSHIP TO VALUE: STRATEGIC MARKET ACCESS PLANNING & EXECUTION

Pricing of new medicines has been to the fore in controversy in 2015, from the reactions to the price of Sovaldi in the treatment of hepatitis to the launch of the Sloan Kettering Drug Abacus and the launch of the ASCO Value Framework. The Pharma & Biotech industry has the opportunity to improve the communication of value of innovative medicines, while ensuring a close relationship with delivering value to the health care system. Proponents of value by disease area include Pharma Benefit Management companies such as Express Scripts in the USA. This has been followed by companies such as Novartis stating their intention to explore pricing by disease area based on specific value in that disease.

However this is more than simply calculating a single parameter such as the change in median overall survival and attaching a value to this, as there are many components of value, including the patient experience. This symposium will explore the different components of value in new medicines in the context of innovative therapies with different patterns of response to more traditional medicines. This symposium will explore how strategic statistical, economic & clinical methodologies, together with an increasing use of Real World Evidence, can be used more effectively to ensure health care systems gain access to life saving and life enhancing medicines, in a sustainable and affordable way, by better understanding those key components which constitute value.

The symposium will also explore practical methodologies which enable price to be more closely linked with value by specific disease area, and also independently of the size of the patient, thus removing one of the important causes of discrimination especially in the use of infused medicines against patients with high BMI.

Moderator:
Colin Wight, Chief Executive, GalbraithWight Ltd., Princeton, New Jersey, USA
WHAT ROLE DO RANDOMISED CLINICAL TRIALS HAVE IN ESTABLISHING THE VALUE FOR HEALTH TECHNOLOGIES?

This educational symposium brings together highly-respected members of the pharmacoeconomics and health technology assessment communities to debate the role of randomised clinical trials (RCTs) in establishing the value for health technologies, in light of the recent ISPOR good research practices task force report on “cost-effectiveness analysis alongside clinical trials”.

• The debate will open with an affirmative statement from Scott Ramsey setting out the role of RCTs for cost-effectiveness analysis.
• The first rebuttal will be led by Mark Sculpher who will argue that models, not trials, should be the basis of resource allocation.
• The second affirmative statement will come from Andrew Briggs who will present the case for using large trials as a basis for establishing key clinical and epidemiological relationships for economic analysis.
• The second rebuttal will come from Andrew Davies who will discuss the importance of utilising RCT evidence within models to establish the value of health technologies.

The overarching goal of the debate is to combine methodology and policy with wit in order to educate and stimulate, and ultimately, to promote more thoughtful use of RCT evidence for policy- and decision-making. Attendees will be encouraged to contribute to the debate, which will culminate in a vote from the audience.

Moderator:
Elisabeth Fenwick, PhD, Director of Health Economics, ICON Health Economics & Epidemiology, Oxford, UK

THE RCT IS THE GOLD STANDARD FOR UNDERTAKING COST-EFFECTIVENESS ANALYSIS

Speaker:
Scott Ramsey, MD, PhD, Member, Fred Hutchinson Cancer Research Center and Professor, Department of Medicine, University of Washington, Seattle, WA, USA

TRIALS ARE A NECESSARY BUT NOT SUFFICIENT BASIS FOR DECISION MAKING

Speakers:
Mark Sculpher, PhD, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK
Andrew Briggs, DPhil, Professor of Health Economics, Health Economics and HTA, Institute of Health & Wellbeing, University of Glasgow, Glasgow, UK
Andrew Davies, Director of Health Economics, ICON Health Economics & Epidemiology, Oxford, UK

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EMERGING USE OF REAL-WORLD EVIDENCE IN EUROPEAN HEALTH CARE

This symposium will discuss comparative methods and insights that new economic stakeholders in key European markets, such as health systems, hospitals, and at-risk providers, are applying to assess value for drug usage in the real world, versus in clinical trials. In-depth insight into two key areas central to this topic will be provided. First, we will examine how health systems and providers in the United Kingdom are using different mechanisms to identify complete episodes of care for patients, and provide a centric view for comparative analysis, relative value and patient risk stratification as part of a holistic population health approach. We will then discuss how commissioning agents, hospitals and these new economic payers view both pay-for-performance and the value in going beyond the condition to treat the whole patient to create better outcomes.

Moderator:
Brian Kelly, MS, President, Life Sciences, Optum, Horsham, PA, USA

Speakers:
Mark Leenay, MD, MS, Chief Medical Officer, Senior Vice President, Optum International, London, UK
Omar Ali, BSc(Hons)Pharm, DipClinPharm, MRPharmS, ACPP, Pharmacy Director, QIPP Adviser Commissioning Payer Network & ERG Cost Impact Modelling for NICE, London, UK

TUESDAY, 10 NOVEMBER | 7:30-8:30 | Brown 3 (L2)

NEW APPROACHES TO CAPTURING VALUE IN ONCOLOGY

The symposium explores further new methods and approaches to capturing value in innovative oncology projects. The impact of HTA assessment being based on less mature evidence is explored, as are the need for clinical and patient viewpoints to be included when assessing value.

Moderator:
Wolfgang Greiner, PhD, Professor of Health Economics and Health Management, Bielefeld University, Bielefeld, Germany

Speaker:
David Chao, BMBCch, FRCP, DPhil, Consultant Medical Oncologist, Royal Free Hospital, London, UK
Scott Ramsey, MD, PhD, Professor of Medicine, Fred Hutchinson Cancer Research Center, Seattle, WA, USA
Isabelle Durand-Zaleski, MD, PhD, Professor of Public Health, URC Eco Île-de-France Hôpital de l’Hotel Dieu and Director, URC Eco, Île-de-France, Paris, France
This symposium will discuss the different perspectives and lessons learned from individuals across multiple disciplines. This will include discussions regarding the development of clinical outcome assessment strategies to support product registration; effective collaboration with patient advocacy groups and clinicians; and creation of economic models to support health technology assessment. Ms. Deal will speak to the challenges and opportunities when developing COA measurement strategies to support the registration of products intended to treat rare conditions. Her presentation will include discussion of the development of novel COAs in these patient populations (when required), including planning and implementing successful qualitative studies and partnering with patient advocacy organizations. Implications for the evaluation of COAs in the context of smaller clinical trial samples will also be discussed. Professor Fricke will speak to the challenges and opportunities payers face surrounding rare and orphan disease treatment decision making. What are the evidence requirements needed for positive appraisals and implications given the small and heterogeneous patient populations being assessed. Mr. Knight will speak to the challenges and opportunities that manufacturers face providing clinical and economic arguments to support treatments in rare diseases. He will explore how best to utilize the limited availability of data and the importance of support from clinician and patient advocacy groups.

Moderator:
Susan Martin, MSPH, Head of Patient-Reported Outcomes, RTI Health Solutions, Ann Arbor, MI, USA

CLINICAL OUTCOME ASSESSMENTS (COA) IN RARE DISEASES: STRATEGY AND IMPLEMENTATION
Speaker:
Linda S. Deal, MSc, Senior Director and Head of Patient-Centered Outcomes Measurement, Pfizer, Collegeville, PA, USA

RARE/ORPHAN DISEASE EVIDENCE REQUIREMENTS TO SUPPORT REIMBURSEMENT AND HEALTH TECHNOLOGY ASSESSMENTS
Speaker:
Frank-Ulrich Fricke, PhD, Professor of Health Economics, Georg-Simon-Ohm University of Applied Science, Nurnberg, Neumarkt, Germany

RARE DISEASES: THE CHALLENGES WE FACE DEVELOPING ECONOMIC MODELS TO SUPPORT HTA SUBMISSIONS
Speaker:
Chris Knight, MSc, Senior Director of Health Economics, RTI Health Solutions, Manchester, UK

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ENRICHED REAL-WORLD DATA (RWD) STUDIES: TAPPING INTO THE GROWING USE OF PATIENT LEVEL DATA TO OPTIMIZE OBSERVATIONAL STUDY DESIGN AND EXECUTION

The increasing demand for real-world evidence (RWE) to support a product’s value proposition, effectiveness, and safety across markets is clear. The question for manufacturers is how to meet that demand through prospective observational studies in a cost-effective and timely way. While many are comfortable looking purely to electronic patient data (e.g., electronic medical records - EMRs) as a source for retrospective database analysis, they often aren’t aware of the important role that these sources can play in primary data collection to generate the rich clinical data needed. This symposium establishes such an alternative – enriched RWD studies – and outlines how manufacturers can not only use them for targeted studies but to create more enduring evidence platforms, with examples. An enriched RWD study is a term describing an observational study for which de novo data collection supplements the existing information present in the patient information. These include, but are not limited to the use of technology embedded into an EMR system to prompt for additional variables to be collected during patient visits and/or site or patient randomization. The use of technology allows seamless data integration into the current patient visit, minimizing health care provider impact. Pragmatic trials with EMR follow-up can also be used to evaluate the impact of various approaches to enhancing adherence, with modest expenditures compared to traditional randomized clinical trials. In addition, data can be collected directly from the patient, providing missing insights about the patient experience when relying on physician-reported data alone. In this symposium, we will discuss these processes as well as applications for enriched RWD studies. We will show how they can lead to more robust and more efficient studies. For example, analyzing the existing EMRs enables study sponsors to identify sites for recruitment where large numbers of eligible patients are being seen, helping to plan/forecast observational studies timelines. We will present case studies demonstrating the benefit for customers, physicians, and other stakeholders. Industry experts will provide points of view related to the challenges of Enriched EMR Studies and possible solutions. Faculty will include provider and industry representatives from the region and senior experts from IMS Health and scientists from Quintiles Real-World Research.

Moderator:
Alison Bourke, MSC, MRPharmS, Scientific Director Real-World Evidence Solutions, IMS Health, London, UK

Speakers:
Joshua Hiller, MBA, Senior Principal, IMS Health, London, UK
Pierre Engel, PharmD, MPH, PhD, Associate Director Epidemiology, Real-World & Late Phase Research, Quintiles, Levallois-Perret Cedex, UK
Andrew Shaw, PhD, RWE Alliance Director, AstraZeneca, Alderley Park, UK
Lance Brannman, PhD, Group Director for Health Economics & Payer Analytics, Center for Health Economics at Gothenburg University, Gothenburg, Sweden

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Please see page 6 for Congress Program Committee Chairs.

The following ISPOR members were volunteer reviewers for this meeting. ISPOR would like to acknowledge and thank them for their contributions to the Congress.

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Cost-Effectiveness Analyses of Transcatheter Aortic Valve Replacement
(Research Posters L, abstract P0364)

Adoption and Utilization Patterns for Transcatheter Aortic Valve Replacement
(Research Posters L, abstract PM145)

Wedneday, November 11 • 8:45 am–1:45 pm
Economic Study Design for Orbital Atherectomy Treatment of Below-the-Knee PAD
(Research Posters V, abstract PRM230)

Better Analysis for Better Decisions
Daniel Malone, PhD, RPh

Daniel C. Malone, RPh, PhD, FAMCP, is a Professor of Pharmacy at the University of Arizona College of Pharmacy, with cross appointment in the Mel and Enid Zuckerman College of Public Health at the University of Arizona. Dr. Malone leads the Comparative Effectiveness Research Group at the University of Arizona and is the former Director of Pharmaceutical Policy and Outcomes with the Center for Health Economics and Outcomes Research. He was the Director of the Pharmaceutical Outcomes research core of the Arizona Center for Education and Research on Therapeutics.

Dr. Malone joined the University of Arizona in 1999 after serving as an assistant professor at the University of Colorado Health Sciences Center. He obtained his Bachelor of Science degree (magna cum laude) from the University of Colorado Health Sciences Center, and earned his MS and PhD degrees from The University of Texas at Austin. Following his formal studies Dr. Malone moved to Seattle for an Agency for Healthcare Research and Quality supported post-doctoral fellowship at the University of Washington.

Dr. Malone has conducted and published cost-effectiveness analyses, burden-of-illness studies, patient reported outcomes studies, and numerous evaluations of health care interventions in real-world environments. Dr. Malone has over 120 peer-review research publications and has obtained over $15 million in extramural funds for his research programs.

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Lorenzo G. Mantovani graduated with a degree in Economics at Bocconi University, Milan. He then went on to obtain a Doctorate in Epidemiology at Erasmus University Rotterdam, The Netherlands. In 2005, he was awarded the ISPOR Distinguished Service Award and the EFPIA Scientists of Tomorrow Award in 2008. He was also candidate for the position of ISPOR President-Elect in 2008.

He is currently an Associate Professor of Public Health at the Research Centre of Public Health at the University of Milan-Bicocca, Milan, Italy. His main research interests include the economics and outcomes of rare diseases and the analysis of compliance and persistence in chronic treatments. He serves or has served as advisor to several health authorities, including the Italian Senate Commission for Health and the Lombardy Region Healthcare Commission.

Professor Mantovani is President of the Italian Association for Pharmacoeconomics and Outcomes Research (2014-2016), President (interim) of the Board of Directors of the ISPOR Italy-Milan Chapter, and is Scientific Director of Charta Foundation in Milan, Italy.


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Dr. François Meyer is currently Advisor to the President of the French National Authority for Health (HAS, Haute Autorité de Santé), in charge of International Affairs. He is a member of the board of directors of HTAI, the international professional society for HTA, and INAHTA, the international network for HTA agencies.

François Meyer joined HAS in 2005 with the responsibility of setting up the Health Technology Assessment (HTA) Division, which he led until 2011. Prior to joining HAS, Dr. Meyer worked at the French Health Products Agency, as Deputy Director of the Regulatory Division (1997-2001), and then as Director of the Drugs and Devices HTA Division (2002-2004). Before this position, he served for 10 years at the teaching hospitals of Montpellier as a practicing physician and then five years in the R&D Division of a pharmaceutical company.

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Jerome Boehm has a financial educational background. He has been working as a consultant in the private sector, in the fields of financial audits and mergers and acquisitions.

He joined the European Commission in 1998 and served various policy functions in the domains of international trade, animal health and public health. Since 2009, he has been in charge of the European Cooperation on Health Technologies Assessment, eHealth and data protection for health.

Finn Børlum Kristensen, MD, PhD

Finn Børlum Kristensen is Chairman of the Executive Committee of the European Network for Health Technology Assessment (EUnetHTA), Director of its Coordinating Secretariat, Danish Health and Medicines Authority (DHMA), Denmark since 2009, and Adjunct Professor in Health Services Research and Health Technology Assessment at University of Southern Denmark since 1999. He is a former Director of the Danish Centre for Health Technology Assessment (DACEHTA), Denmark from 1997-2009.

Dr. Børlum Kristensen is a university graduate in medicine and holds a PhD in Epidemiology, with specialty in General Practice and in Public Health. He has worked on international projects in health services research, epidemiology, health technology assessment, and clinical practice guidelines since the 1980s. He was Chairman of INAHTA in 2003-2006; Project Leader of EUnetHTA in 2006-2008; Editor of Health Technology Assessment Handbook (English, translated), 2007; and Chief Editor of three peer-reviewed publication series from DACEHTA in 1998-2009. He has been on the ISPOR Board of Directors and is currently Chairman of the ISPOR HTA Council.

Nancy Devlin, PhD

Nancy Devlin, PhD, is Director of Research at the Office of Health Economics (OHE). She has a PhD in Economics and a BA (first class with honours) in Economics, both from the University of Otago, New Zealand. Prior to joining OHE in 2009, Nancy was Professor of Economics at City University, where she was Head of the Economics Department and Acting Dean of Social Sciences. Her senior academic leadership roles have included responsibility for major organisational changes. She has over 25 years of experience as a researcher and advisor to health care organisations, both in the public and private sectors in the UK and internationally.

Nancy holds honorary positions at the Centre for Health Economics, University of York; Cass Business School, London; and City University, London. Between 2011 and 2014 she served as the elected chair of the Executive Committee of the EuroQol Group, a network of international, multilingual, multidisciplinary researchers that developed the EQ-5D.

In that role, she had overall responsibility for the scientific strategy of the EuroQol Group and successfully implemented important improvements to the way the Group functioned.

Highly regarded as a presenter and educator in health economics, Nancy was awarded the UK Higher Education Academy prize for outstanding economics lecturer (2004) and was the founder of the Health Economics Education (HEe) website. Nancy has published over 100 original peer-reviewed journal articles on a wide range of empirical, methodological and theoretical topics in health economics, health policy, and outcomes research. Her work has won prizes for research excellence (City University, 2005) and best scientific paper (EuroQol Group, 2014). She is co-author of numerous books, including Economic Analysis in Health Care, a leading textbook on health economics now in its second edition.

A. Brett Hauber, PhD

A. Brett Hauber, PhD, is Senior Economist and Global Head of Health Preference Assessment at RTI Health Solutions. He has more than 10 years of academic, research, and government experience in health and environmental economics. His primary area of specialization is discrete choice analysis of revealed- and stated-preference data. He also has extensive experience in conducting benefit-risk analysis of patients and other health care decision makers and in estimating health-state utilities. His most recent applied work has included discrete-choice experiments of patient and physician benefit-risk preferences for treatments for conditions, including Alzheimer’s disease, HIV, vasomotor symptoms, Crohn’s disease, idiopathic thrombocytopenia purpura, type 2 diabetes, and irritable bowel syndrome. He has also studied the theoretical and empirical relationships among various health utility measures. Dr. Hauber regularly teaches courses on conjoint analysis and health-state utility estimation. Dr. Hauber’s research has been published in numerous health and medical journals, including Value in Health, Pharmacoeconomics, Quality of Life Research, Journal of Women’s Health, Medical Care, Clinical Therapeutics, ISPOR Connections (now called Value & Outcomes Spotlight), The Patient, Supportive Care in Cancer, AIDS Patient Care and STDs, and Alzheimer Disease and Associated Disorders.

Hans-Georg Eichler, MD, MSc

Hans-Georg Eichler, MD, MSc, is the Senior Medical Officer at the European Medicines Agency EMA in London, UK, where he is responsible for coordinating activities between the Agency’s scientific committees and giving advice on scientific and public health issues.

Prior to joining the European Medicines Agency, Dr. Eichler was at the Medical University of Vienna in Austria for 15 years. He was Vice-Rector for Research and International Relations since 2003, and Professor and Chair of the Department of Clinical Pharmacology since 1992. His other previous positions include President of the Vienna School of Clinical Research and Co-Chair of the Committee on Reimbursement of Drugs of the Austrian Social Security Association. His industry experience includes time spent at Ciba-Geigy Research Labs, UK, and Outcomes Research at Merck & Co., in New Jersey. In 2011, Dr. Eichler was the Robert E. Wilhelm Fellow at the Massachusetts Institute of Technology’s Center for International Studies, participating in a joint research project under the MIT’s NEWDIDS initiative.

Dr. Eichler graduated with an MD from Vienna University Medical School and a Master of Science degree in Toxicology from the University of Surrey in Guildford, UK. He trained in internal medicine and clinical pharmacology at the Vienna University Hospital, as well as at Stanford University.
Maarten J. IJzerman, PhD

Maarten J. IJzerman is a full professor of clinical epidemiology & HTA at the University of Twente. He is the dean of Health and Biomedical Technology in the School for Science and Technology, which is responsible for the academic programs in Technical Medicine, Biomedical Engineering, and Health Sciences.

Maarten and his team work on methods to evaluate the benefits of diagnostic and imaging technologies for personalized medicine and on the application of outcomes research to evaluate stakeholders’ value and the health economic impact of medical technologies in development. Maarten is a pioneer in the field of early Health Technology Assessment and Multi-Criteria Decision Analysis for healthcare. He currently is involved in several initiatives to develop emerging good practices for applying Simulation Modelling in Healthcare Delivery research. Maarten has more than 130 peer-reviewed articles in the intersection of engineering, medicine and outcomes research.

Maarten has been an active ISPOR member since 2004 and a member of the Board of Directors between 2013-2015. He serves on numerous national and international boards and is the chair of the Dutch pharmacoeconomic guidelines committee of Zorginstituut Nederland.

Mirella Marlow, MA, MBA

Mirella Marlow is responsible for NICE’s programmes for evaluating and developing evidence on medical devices and diagnostics, and works with the medtech industry, health services, government policy makers, lifesciences organisations and researchers to maximise the effectiveness of NICE’s work in these areas. She joined NICE in 2004, having previously worked for 15 years in senior roles for various payers in the English National Health Service. Mirella has an MBA and a Masters in Medical Ethics and Law from Keele University, where her interests included the ethics of measuring the cost-effectiveness of interventions to improve the safety of health care, and legal cases relating to health care rationing. She is a contributor to work with the European Network for Health Technology Assessment (EUnetHTA) on integrating ethical considerations when determining the value of health technologies.

Kevin Marsh, PhD

Kevin Marsh, PhD, is Senior Director of Modelling and Simulation at Evidera. His research interests include the use of economic and decision analysis to inform health decisions, including pipeline optimisation, authorisation, reimbursement, and prescription decisions. He specialises in decision modelling, MCDA, and a range of economic valuation methods, such as stated preference value approaches. He actively contributes to the methodological development of these techniques. He is currently co-chairing the International Society for Pharmacoeconomics and Outcomes Research Taskforce on the use of MCDA in Health Care Decision Making. He has applied these and other research techniques for a range of organisations, including both regulatory and industry clients. Dr. Marsh completed his PhD at the University of Bath, specialising in economic valuation techniques. After a year at Oxford University, he joined the Matrix Knowledge Group in London, where he built their economics practice. Dr. Marsh is an active member of the Campbell and Cochrane Economic Methods Group.

Mônica D. Oliveira, PhD

Mônica D. Oliveira, PhD is Associate Professor of Decision Sciences at the Department of Engineering and Management, Instituto Superior Técnico (IST), University of Lisbon, and member of the research team of CEG-IST, the Centre for Management Studies of IST. Her research interests include the development of management science models to assist policy and decision makers in health and clinical settings, with a special interest in multi-criteria value modelling using participatory processes. She has enhanced and applied management science techniques in multiple public and private organizations. She has published her research in Operations Research, Management Science, and Health Economics and Management international journals. She has been active in participating in international health projects, has been involved in advisory boards from the Portuguese Ministry of Health, and is an active member of the Portuguese Association of Health Economics and of the EURO Working Group on Operational Research Applied to Health Services.

Brian O’Rourke, PharmD

Dr. Brian O’Rourke is the President and Chief Executive Officer of the Canadian Agency for Drugs and Technologies in Health (CADTH). He joined CADTH in January of 2009 as Vice-President of the Common Drug Review following a distinguished career as a Pharmacist and Health Services Operations Officer with the Canadian Forces. With over 30 years of experience in health care, Dr. O’Rourke actively positions CADTH as the leading source of health technology information in Canada. Dr. O’Rourke holds a Bachelor of Science in Pharmacy from Dalhousie University and a Doctor of Pharmacy from the University of Toronto. Dr. O’Rourke is the current Chair of the International Network of Agencies for Health Technology Assessment (INAHTA).

Sergio Pecorelli, MD, PhD

Sergio Pecorelli, MD, PhD, is Professor of Gynecology and Obstetrics and Chancellor (Rettore) (November 1, 2010 – present) at the University of Brescia, Health & Wealth, Italy. Dr. Pecorelli is also President of the Management Board of the Italian Medicines Agency (AIFA) (June 11, 2009 – present) and of the Giovanni Lorenzini Foundation (Milan and Houston).

Dr. Pecorelli is the Italian Government representative in the EU High Level Steering Group of the European Innovation Partnership on Active and Healthy Ageing. He is Chairman of the International Scientific Advisory Board of the Camillo Golgi Foundation for Biomedical Research (Brescia, Italy).

Previously, Dr. Pecorelli was the Chairman of the Italian National Committee for Cancer Prevention, Member of the Board of Trustees of the Italian National Institutes of Health, President of the International Gynecologic Cancer Society, and Chairman of the EORTC Gynecologic Cancer Cooperative Group.
His scientific activity is almost entirely devoted to female cancer, with more than 300 scientific papers, and during his clinical activity he performed more than 7,000 surgical procedures.

Dr. Pecorelli was awarded the Gold Medal for Public Health Services by the President of the Republic of Italy in 2004, and the title of Grand’Ufficiale della Repubblica in 2014. He is Honorary Member of the American College of Surgeons and of the American College of Obstetricians and Gynecologists.

Walter Ricciardi, MD, MPH, MSc
Walter Ricciardi is Professor of Hygiene and Public Health at the Catholic University of the Sacred Heart in Rome, where he is also Director of the Department of Public Health and Director of the local School of Public Health. In September 2015, he was appointed President of the Italian National Institute of Health (Istituto Superiore di Sanità) where he was Commissioner from July 2014 to July 2015.

In 2010, Dr. Ricciardi was elected President of the European Public Health Association (EUPHA) and in 2011 he was reelected for a second term until 2014. In 2011 he was appointed Member of the European Advisory Committee on Health Research to the WHO European Regional Director for three years and elected Member of the Executive Board of the National Board of Medical Examiners in the United States.

Dr. Ricciardi manages several undergraduate and postgraduate teaching activities. Among them is a Masters of Science programme and International Courses in Epidemiology. In Italy, he has sat in the Higher Health Council of the Ministry of Health from 2003-2006 and 2013-2016. In 2010, the Minister of Health of Italy appointed him to the Higher Health Council where he chairs the Public Health Section.

In May 2013, Dr. Ricciardi was appointed Member of the Expert Panel on effective ways of investing in Health (European Commission, DG – Sante). He is Editor of the European Journal of Public Health and the Oxford Handbook of Public Health Practice and Founding Editor of Epidemiology, Biostatistics, and Public Health (formerly the Italian Journal of Public Health).

Anthony John (Tony) Culyer, CBE, BA, Hon DEcon, Hon FRCP, FRSA, FMedSci
Tony Culyer is Emeritus Professor of Economics at York (England); Chair, NICE International Advisory Group, London, England; Senior Fellow at the Institute of Health Policy, Management and Evaluation, University of Toronto; Adjunct Scientist, Institute for Work and Health, Toronto; and Distinguished Visiting Scholar, University of the Witwatersrand, South Africa. He was the founding Organiser of the Health Economists’ Study Group. For 33 years he was the founding co-editor, with Joe Newhouse, of Journal of Health Economics. He was founding Vice Chair of the National Institute for Health and Care Excellence (NICE). For many years he was chair of the Office of Health Economics in London. He is Editor-in-Chief of the on-line Encyclopedia of Health Economics. He was responsible for the 1994 report that led to the redesign of the NHS’s R&D system. For many years he was chair of the Department of Economics & Related Studies at York and, for six of them, was also deputy vice-chancellor. He has published widely, mostly in health economics. The third edition of his The Dictionary of Health Economics (Edward Elgar) came out in 2014. A collection of his non-technical essays called The Humble Economist is available on-line free of charge.

Mario Strazzabosco MD, PhD, FACG
Mario Strazzabosco MD, PhD, FACG, is Professor of Gastroenterology at the University of Milan-Bicocca, where he is also Chair of the Department of Translational Medicine and Surgery and Chief of the Section of Digestive Disease at the San Gerardo Hospital in Monza, Italy. Dr. Strazzabosco is also Adjunct Professor of Medicine and Deputy Director of the Liver Center at Yale University, CT, USA. Trained at the University of Padova, Dr. Strazzabosco, was Chief of GI and Medical Director of Liver Transplantation at the Ospedali Riuniti di Bergamo, before being recruited by Yale University as Pessor of Medicine and Director of Transplant Hepatology. Dr. Strazzabosco is both a translational scientists with a strong publication record in liver pathophysiology/repair, and a practicing Hepatologist with an interest in Liver Transplantation and Liver Cancer. Dr. Strazzabosco is also interested in outcome research and in putting in practice the Value Based Medicine approach.

Praveen Thokala, MASc, PhD
Praveen Thokala, MASc, PhD is a Research Fellow in the School of Health and Related Research (ScHARR) at the University of Sheffield. He joined ScHARR after completing an MASc from the University of Toronto and a PhD from the University of Southampton. His research interests include multi criteria decision analysis (MCDA), health technology assessment, simulation modelling and optimisation. He is currently co-chairing the ISPOR Task Force on the use of MCDA in health care decision-making and has been involved in a number of MCDA studies, including supporting priority setting and benefit-risk analysis.

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Lucas M.A. Goossens, PhD

Lucas M.A. Goossens, PhD, Assistant Professor of Quantitative Analysis, Erasmus University, institute for Health Policy & Management, Rotterdam, The Netherlands


Lucas Goossens is an Assistant Professor of Quantitative Analysis at the institute of Health Policy and Management (IBMG) and the institute for Medical Technology Assessment (iMTA) of Erasmus University Rotterdam in the Netherlands. His research is centered around economic evaluations in healthcare and broader epidemiological studies. He has published in health economic, medical, and epidemiological journals on topics such as interventions in pulmonary diseases, patient preferences, hospital-at-home schemes, and medication adherence. He has a special interest in innovative epidemiological considerations and statistical methods in economic evaluations, medical trials and epidemiological studies, including discrete choice experiments. He holds a PhD and MSc in health economics and an MA in History. Before he became a health scientist, he worked as a political journalist, specialized in fiscal, economic, and healthcare policy. He currently serves as the Director of the Research Master program of IBMGs and the Netherlands Institute for Health Sciences.

ABSTRACT

Objectives: This study aimed 1) to quantify the strength of patient preferences for different aspects of early assisted discharge in The Netherlands for patients who were admitted with a chronic obstructive pulmonary disease exacerbation, and 2) to illustrate the benefits of latent class modeling of discrete choice data. This technique is rarely used in health economics. Methods: Respondents made multiple choices between hospital treatment as usual (7 days) and two combinations of hospital admission (3 days) followed by treatment at home. The latter was described by a set of attributes. Hospital treatment was constant across choice sets. Respondents were patients with chronic obstructive pulmonary disease in a randomized controlled trial investigating the cost-effectiveness of early assisted discharge and their informal caregivers. The data were analyzed using mixed logit, generalized multinomial logit, and latent-class conditional logit regression. These methods allow for heterogeneous preferences across groups, but in different ways. Results: Twenty-five percent of the respondents opted for hospital treatment regardless of the description of the early assisted discharge program, and 46% never opted for the hospital. The best model contained four latent classes of respondents, defined by different preferences for the hospital and caregiver burden. Preferences for other attributes were constant across classes. Attributes with the strongest effect on choices were the burden on informal caregivers and co-payments. Except for the number of visits, all attributes had a significant effect on choices in the expected direction. Conclusions: Considerable segments of respondents had fixed preferences for either treatment option. Applying latent class analysis was essential in quantifying preferences for attributes of early assisted discharge.

Rok Hren, PhD

Rok Hren, PhD, MSc, President, ISPOR Slovenia Chapter, Assistant Professor, University of Ljubljana, Managing Director of Carso, a Member of Salus Group PLC (SALR.SI), Ljubljana, Slovenia


Rok Hren, PhD, has more than 15 years of commercial experience in pharmaceutical industry, with more than 10 years on a board level in both line management, which has included full P&L responsibility for operations in Slovenia and Romania, and regional leadership functions in Central and Eastern Europe. He regularly presents on the topic of pharmaceutical economics and policies at conferences in Europe and is well experienced in health care media business. Currently, he holds the position of a Managing Director of Carso, a Member of Salus Group PLC (SALR.SI). He received his PhD in Physiology and Biophysics from Dalhousie University, Canada and MSc in International Health Policy (Health Economics) with distinction from London School of Economics and Political Science, UK. He is also an Assistant Professor at the University of Ljubljana and a President of ISPOR Slovenia Regional Chapter. In total, his publications gathered 240/341 citations (excluding self-citations) in WoS/Scopus (as of September 16, 2015).

ABSTRACT

Objective: In this study, we examined the impact of the Pharma Economic Act, which was introduced in Hungary in 2007. Methods: We used detailed data on the Hungarian prescription drug market, which had been made publicly available by the authorities. We evaluated the effect of the Pharma Economic Act on both dynamic and static efficiencies and also on equity, which has been historically a controversial issue in Hungary. We analyzed the overall prescription drug market and statin and atorvastatin markets; as a proxy for determining dynamic efficiency, we examined the oncology drug market for some specific products (e.g., bortezomib) and the long acting atypical antipsychotic drugs market. Results: There is no denying that the authorities managed to control the overall prescription drug costs; however, they were still paying excessive rents for off patent drugs. Examples of oncology and long-acting atypical antipsychotic drugs showed that the diffusion of innovation was on per capita basis at least comparable to G-5 countries. While the share of out-of-pocket co-payments markedly increased and the reimbursement was lowered, the concurrent price decreases often meant that the co-payment per milligram of a given dispensed drug was actually lower than that before the Act, thereby benefiting the patient. Conclusions: It appears that strong mechanisms to control volume rather than price on the supply side (marketing authorization holders) contained the drug expenditure, while offering enough room to strive for innovation. Making data on prescription drug expenditures and associated co-payments publicly available is an item that should be definitely followed by the surrounding jurisdictions.
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7-11 November 2015 | MiCo – Milano Congressi | Milan, Italy

EXHIBIT PROGRAM

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EXHIBIT FLOOR PLAN

South Hall

Exhibits on view:
Monday, 9 November
8:30-19:45
Tuesday, 10 November
8:30-19:15
Wednesday, 11 November
8:30-15:00

Lunch, Coffee Breaks and Receptions held in the Exhibit-Poster Hall.

Monday, 9 November
Coffee Break 10:45-11:15
Lunch 12:15-14:15
Coffee Break 15:15-15:45
Exhibitors’ Open House Reception 18:00-19:45

Tuesday, 10 November
Coffee Break 9:45-10:15
Lunch 12:00-13:45
Coffee Break 14:45-15:15
Exhibitors’ Wine & Cheese Reception 17:30-19:15

Wednesday, 11 November
Coffee Break 9:45-10:00
Lunch 12:45-13:45
Coffee Break 14:45-15:00

Please enjoy the many Networking Lounge Areas on the Exhibit Hall floor.
### EXHIBITING ORGANIZATIONS

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Table 7

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**Plenary Session** – Wed, 11 Nov, 11:15 - 12:30
Presentation of the Task Force Reports: Emerging Good Practices for Conducting MCDA

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W4 – Mon, 9 Nov, 17:00 - 18:00  Making Sense of Novel Approaches for Indirect Comparison: Similarities and Differences of Simulation and Matching Based Approaches

W10 – Tue, 10 Nov, 8:45 - 9:45  Moving the Science Forward: Tackling Key Psychometric and Methodological Issues Facing the Field of Clinical Outcomes Assessment


W33 – Wed, 11 Nov, 15:00 - 16:00  Uncertainty of Uncertainty Estimates in Economic Modelling of Oncology

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**Table 12**

**Booth 511**

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Accelerating Cures: Addressing Unmet Patient Need or Putting Patients at Risk?

**TUESDAY, MAY 24: SECOND PLENARY SESSION**
Making Medical Decisions in an Irrational World

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• New! Clinical Outcomes Assessment – A Conceptual Foundation
  Value in Health September/October 2015
• Selecting a Dynamic Simulation Modeling Method for Health Care Delivery Research – Part 2
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• Cost-Effectiveness Analysis Alongside Clinical Trials II
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• Applying Dynamic Simulation Modeling Methods in Health Care Delivery Research – The SIMULATE Checklist
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### 2016

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Abstract Submission Deadline: Thursday, January 14, 2016  
Early Registration Deadline: Tuesday, April 12, 2016 |                                       |
| **7th Asia-Pacific Conference**                                     | 3-6 September 2016        | Suntec Convention Center, Singapore | Abstract Submission Opens: Monday, 16 November 2015  
Abstract Submission Deadline: Thursday, 17 March 2016  
Early Registration Deadline: Tuesday, 19 July 2016 |                                       |
| **19th Annual European Congress**                                   | 29 October-2 November 2016| Austria Center Vienna, Vienna, Austria | Abstract Submission opens: Monday, 21 March 2016  
Abstract Submission deadline: Tuesday, 21 June 2016  
Early Registration Deadline: Tuesday, 20 September 2016 |                                       |

### 2017

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| **22nd Annual International Meeting**                               | May 20-24, 2017           | Boston, MA, USA                  | Abstract Submission Opens: Wednesday, October 19, 2016  
Abstract Submission Deadline: Thursday, January 19, 2017  
Early Registration Deadline: Tuesday, April 11, 2017 |                                       |
| **6th Latin America Conference**                                    | 14-16 September 2017      | São Paulo, Brazil                | Abstract Submission Opens: Monday, 23 January 2017  
Abstract Submission Deadline: Thursday, 23 March 2017  
Early Registration Deadline: Tuesday, 18 July 2017 |                                       |
| **20th Annual European Congress**                                   | November 2017              | Glasgow, Scotland                | Abstract Submission Opens: Monday, 27 March 2017  
Abstract Submission Deadline: Tuesday, 27 June 2017  
Early Registration Deadline: Tuesday, 19 September 2017 |                                       |