Over 4800 attendees in 2014! Save the Date

ISPOR 18th Annual European Congress



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

Impacting Health Decision Making with Outcomes Research: Closing the Gap

CALL FOR ABSTRACTS ABSTRACT SUBMISSION DEADLINE: 23 JUNE 2015

preliminary program information

MONDAY, 9 NOVEMBER

FIRST PLENARY SESSION

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 the New Medical Device Regulation in Europe as well as the work underway within the Adaptive Pathways to Patients initiative for drugs. The panel will present candid views on adaptive pathways as the preferred approach to developing, licensing, assessing, appraising, and paying for new medicines and treatments. This session will also examine the European Commission's HTA network plans following the transition of the successful EUnetHTA program, which built strength and dialogue both across Europe and globally. * 48 Research Podium Presentations * 5 Issue Panels * 6 Workshops * 6 ISPOR

Group Forums * Exhibits * 800 Research Poster Presentations – Session I & II

TUESDAY, 10 NOVEMBER

SECOND PLENARY SESSION

Outcomes Research: Are We Ready to Put Theory into Practice? 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

CONGRESS PROGRAM COMMITTEE CO-CHAIRS

Lorenzo G. Mantovani, DSc, Associate Professor of Public Health, Center for Public Health Research (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

Lodi Correno in Avia





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.

- * 10 Issue Panels * 12 Workshops * 6 ISPOR Group Forums * Exhibits
- * 800 Research Poster Presentations Session III & IV * Evening Social Event

WEDNESDAY, 11 NOVEMBER

PE 16 THIRD PLENARY SESSION

Recommendations from the ISPOR Multi-Criteria Decision Analysis Emerging Good Practice Task Force and Remaining Controversies

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.

- * 5 Issue Panels *15 Workshops * Exhibits
- * 400 Research Poster Presentations Session V



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short course information

SATURDAY. 7 NOVEMBER

All Day Course 9:00-18:00 **INTRODUCTION TO HEALTH ECONOMIC/** PHARMACOECONOMIC EVALUATIONS

Discuss how to incorporate pharmacoeconomics into study design and data analysis, collect and calculate costs of different alternatives, determine the economic impact of clinical outcomes, and identify, track, and assign costs to different types of health care resources.

Morning Courses 9:00-13:00

INTRODUCTION TO DATABASE ANALYSIS OF **OBSERVATIONAL STUDIES OF TREATMENT EFFECTS**

Review analytic techniques and specific best practices to improve causal inference in database analysis, including the use of stratification analysis before multivariable modeling, multivariable regression, propensity scoring, instrumental variable, and structural modeling techniques. INTRODUCTION TO PATIENT-REPORTED OUTCOMES **ASSESSMENT: INSTRUMENT DEVELOPMENT & EVALUATION**

Instrument development and evaluation includes psychometric analyses such as the use of factor analysis and other techniques. This course covers the recent draft guidance from the FDA as well as existing guidance from the EMEA regarding instrument development.

INTRODUCTION TO MODELING

This course presents an introductory discussion of pharmacoeconomic modeling techniques such as Monte Carlo analysis, Markov modeling, and probabilistic sensitivity analysis.

STATISTICAL METHODS FOR PHARMACOECONOMICS & OUTCOMES RESEARCH

This course introduces statistical concepts with an emphasis on the use of techniques commonly employed in pharmacoeconomics and outcomes research. Concepts such as random variables, statistical estimation, and the use of regression techniques are discussed.

COST-EFFECTIVENESS ANALYSIS ALONGSIDE CLINICAL TRIALS

Review design, conduct, and reporting of costeffectiveness analyses alongside clinical trials. 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 are presented.

ELEMENTS OF PHARMACEUTICAL/BIOTECH PRICING

Discuss key terminology and issues in pricing decisions, tools to build and document product value, the role of pharmacoeconomics, and the differences in payment systems that help shape pricing decisions.

Afternoon Courses 14:00-18:00

INTRO TO HEALTH TECHNOLOGY ASSESSMENT This course covers key elements, methods, and language of health technology assessment (HTA), provides an overview of basic HTA disciplines, and reviews practical steps involved in developing and using HTA reports in different health care systems using real world examples of drugs and devices.

META-ANALYSIS & SYSTEMATIC LITERATURE REVIEW

Analyze four key areas: impetus for network meta-analysis and systematic reviews; basic steps to perform a quantitative systematic review; statistical methods of combining data; and appraisal and use of meta-analytic reports.

NEW! DEVELOPMENT OF CONCEPTUAL MODELS Review the practical aspects of developing conceptual models using a series of case studies to understand the

role of clear conceptual models in the iterative process of model development.

USE OF PROPENSITY SCORES IN OBSERVATIONAL STUDIES OF TREATMENT EFFECT

Evaluate concerns about bias and explain the methods for causal inference in observational studies; assess how propensity scores can reduce bias; and review risk adjustment models, confounding, pros and cons of standard adjustment, and propensity scoring methodology. INTRODUCTION TO PATIENT PREFERENCE METHODS **USED FOR OALYS**

Learn methods for measuring preference-based outcomes, review issues such as potential insensitivity of generic instruments for disease-specific problems, and review the extent to which adaptation of generic or disease-specific quality of life instruments may offer a solution.

PHARMACOECONOMIC MODELING – APPLICATIONS

Gain hands-on experience in constructing a decision analysis tree including Markov models, Monte Carlo simulations, sensitivity analysis, determination of probability values, and transition probabilities.

SUNDAY. 8 NOVEMBER All Day Course 8:00-17:00

BAYESIAN ANALYSIS – OVERVIEW AND APPLICATIONS

This course provides an overview of the Bayesian approach and its applications to health economics and outcomes research. It covers basic elements of Bayesian statistics, contrasting briefly with classical statistics, and introduces available statistical packages. Attendees then apply principles to data analysis problems using WinBUGS.

Morning Courses 8:00-12:00 NEW! INTRODUCTION TO THE ECONOMIC ANALYSIS OF DIAGNOSTICS

Explore the taxonomy and economic aspects of diagnostics: construct a simple conceptual framework for economic evaluation of a diagnostic; learn the key components and types of data required; and review the implications for evidence requirements across different countries.

DISCRETE EVENT SIMULATION FOR ECONOMIC ANALYSES – CONCEPTS

Gain a basic understanding of key concepts of discrete event simulation with focus on the use of these simulation models to address health economic (and device-related) problems.

USE OF INSTRUMENTAL VARIABLES IN OBSERVATIONAL STUDIES OF TREATMENT EFFECTS

Sample selection models provide a test and correction for the presence of selection bias, enabling an investigator to obtain unbiased estimates of treatment effects. Faculty will discuss various models and their applications, in particular instrumental variables.

TRANSFERABILITY OF COST-EFFECTIVENESS DATA **BETWEEN COUNTRIES**

Review factors making economic data more difficult to transfer between countries than clinical data. Discuss methods to assess transferability of foreign cost, effects, cost-effectiveness estimates, and transferability of health state valuation based on the EQ-5D instrument.

CONJOINT ANALYSIS – THEORY & METHODS

Learn the conceptual and empirical basis for using conjoint analysis to elicit preferences in outcomes research. Conceptual basis for quantifying decision-maker preferences - as well as practical design and analytical issues – are presented.

BUDGET IMPACT ANALYSIS I: A 6-STEP APPROACH

This course describes the methods used to estimate the budget impact of a new health care technology. Both static and dynamic methods for estimating the budget and health impact of adding a new drug to a health plan are presented.

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

Interest is growing among payers and producers of medical products for arrangements involving "payfor-performance" or "risk-sharing." Although they have appeal, there can be substantial barriers to their implementation.

Afternoon Courses 13:00-17:00

NEW! RISK SHARING/PERFORMANCE-BASED **ARRANGEMENTS IN CENTRAL & EASTERN EUROPE: IMPLEMENTATION OF MANAGED ENTRY** AGREEMENTS

Explore key features of pricing and reimbursement systems in Central & Eastern European countries. Gain hands-on experience using an Excel-based approach to understand what methods are needed to facilitate evidence-based reimbursement policies of new health technologies.

BUDGET IMPACT ANALYSIS II: APPLICATIONS AND DESIGN ISSUES

Gain hands-on experience utilizing an Excel-based approach to create and modify budget impact analysis models and cost calculators. Applications will focus on design issues related to accuracy of budget impact estimation as well as applicability to decision makers. DISCRETE EVENT SIMULATION FOR ECONOMIC **ANALYSES – APPLICATIONS**

Gain experience using practical hands-on discrete event simulation exercises. Topics include: components of a DES; how to build a model; modeling of processes and resource use; modeling of variables and decisions.

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

Utilize a series of case studies to explore hands-on the different approaches to mixed methods, including Group Concept Mapping (GCM), in order to understand the methodology from both a participant and researcher perspective.

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

Learn the fundamentals and concepts of network meta-analysis. The material in this course is motivated by instructive and real examples. Case studies are implemented with the WinBUGS package.

PATIENT REGISTRIES

Patient registries and their applications in identifying "real world" clinical, safety, and patient-perspective issues, regulatory trends and requirements, operational components, management issues, and measures of program success are discussed.

REIMBURSEMENT SYSTEMS FOR PHARMACEUTICALS IN EUROPE

Using governmental regulation sources and the ISPOR Global Health Care Systems Roadmap, discuss health technology decision-making processes for coverage and reimbursement decisions for pharmaceuticals/biologics in various countries across Europe. Systematically review these reimbursement systems and compare and contrast the key characteristics.

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

Review the use of MCDA in health care applications and the different approaches employed. Issues related to selecting the right data approach, criteria definition, scoring performance, weighting criteria, and uncertainty analysis will be demonstrated.

> **Complete Short Course descriptions** available at www.ispor.org

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abstract submission information

Abstract Submission Begins: 23 March 2015 / Abstract Submission Deadline: 23 June 2015

Submit abstracts and proposals through ISPOR's online abstract submission system by 23 June 2015. SUBMISSION INSTRUCTIONS, EXAMPLES & SPECIFIC EVALUATION CRITERIA AVAILABLE AT www.ispor.org

Submission Descriptions and Topics

RESEARCH ABSTRACTS

Outcomes research on all health care interventions (including drugs, devices, behavioral modification programs, surgery, disease prevention, gene therapy, screening, diagnostic procedures, and health education) and on all diseases or health disorders are considered. Research abstracts (except for conceptual papers) must be organized by OBJECTIVES, METHODS, RESULTS, CONCLUSIONS. All accepted research abstracts are published in *Value in Health* as submitted. Accepted research is presented as a 15-minute podium presentation or poster presentation (with a poster author discussion hour). Abstracts are evaluated on the quality of the study (or concept) and quality of the abstract presentation. A research abstract that was submitted to another meeting and copyright transferred is not allowed.

Research topics include: Clinical Outcomes Studies, Cost Studies, Patient-Reported Outcomes & Patient Preference Studies, Health Care Use & Policy Studies, Research on Methods, Conceptual Papers. See the ISPOR website for research subtopics, diseases, and health care treatments.

ISSUE PANEL PROPOSALS

Issue panel proposals should show real debate on new or controversial issues in health economics and outcomes research or real debate on the use of outcomes research in health care decision making. Issue panel proposals must be organized MODERATOR, PANELISTS, ISSUE, OVERVIEW. Accepted issue panels are one hour in duration with a moderator and 2-3 panelists representing different organizations. Panelists should present distinct views about the topic. Issue Panel topics are: Clinical Outcomes Research Issues, Economic Outcomes Research Issues, Patient-Reported Outcomes & Patient Preference Research Issues, Health Policy Development Using Outcomes Research Issues, Use of Real World Data Issues. See the ISPOR website for issue panel subtopics.

WORKSHOP PROPOSALS

Workshop proposals should show novel and innovative experiences in the conduct of outcomes research (including, but not limited to, experiences with conjoint analysis, large database analysis, modeling, observational studies, record review, surveys, sensitivity analysis, and patient registries) or novel and innovative experiences in the use of outcomes research (clinical, economic, or patient-reported/patient preference outcomes) in health care policy development. Workshop proposals must be organized by DISCUSSION LEADERS, PURPOSE, DESCRIPTION. Accepted workshops are one hour in duration with a minimum of 2 and maximum of 4 discussion leaders (more than one organization must be represented). An audience interactive element must be included in the proposal and during the workshop.

Workshop topics include: Clinical Outcomes Research, Economic Outcomes Research, Patient-Reported Outcomes & Patient Preference Research, Health Policy Development Using Outcomes Research, Use of Real World Data. See the ISPOR website for workshop subtopics.

Why Submit to ISPOR Milan?

ISPOR is recognized globally as the leading educational and scientific organization for outcomes research and its use in health care decisions. The European Congress is the place to share your new research as a podium or poster presentation, interact with attendees during a workshop on your innovative experiences in outcomes research, or debate your views on a controversial topic in an issue panel session.



- Audience: Over 5,000 attendees from the global HEOR community researchers, regulators, decision makers, and global leaders
- Advance the Science: Contribute your research, ideas, and knowledge
- Research Impact: The attendee profile, ISPOR's global recognition, and the promotion and dissemination of meeting content improves the impact of your research
- Career Development: Be part of this international network, become eligible for presentation awards, and be cited in Value in Health (all accepted research included)

No fee for abstract submission. Contribute to the program for ISPOR Milan – the Submission Deadline is Tuesday, 23 June.

Submission Instructions, Examples & Specific Evaluation Criteria Available at: www.ispor.org



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congress information and registration fees

Why Attend ISPOR Milan?

What Does an ISPOR European Congress Offer?

ISPOR is recognized globally as the leading educational and scientific organization for outcomes research and its use in health care decisions. If you want to meet people in the health economics and outcomes research (HEOR) field, discuss the latest trends, and learn from the experts, attend ISPOR Milan.

The ISPOR European Congress features three thought-provoking plenary sessions and more than 2,000 presentations in the form of workshops, issue panels and podium presentations plus posters on innovative research methods, health policy development using outcomes research, patient preferences, real world data, clinical, economic, and patient-reported outcomes.

In addition, ISPOR offers a series of short (training) courses on trending topics in the HEOR field ranging from multi-criteria decision analysis to tried and true modeling, database, economic, preference-based, and outcomes research methodology courses, many with particular relevance to Europe, such as *Reimbursement Systems for Pharmaceuticals in Europe* and *Risk Sharing/ Performance-based Arrangements in Central & Eastern Europe*. These courses range from introductory to advanced and many include hands-on training opportunities.

Who Attends?

The ISPOR scope and sphere of influence includes outcomes researchers, health technology developers and assessors, regulators, health economists, health care policy makers, payers, providers, patients, populations, and society as a whole.

The diversity in work environments and international scope of attendance provide excellent networking opportunities and stimulating discussions and debate.

Why Attend?

- Learn new & novel experiences in the conduct/use of HEOR.
- Stay current via cutting edge plenary sessions and presentations on innovative and controversial issues.
- Share research, ideas, and developments in the field and help advance the science.
- Network and renew connections with clients, colleagues or collaborators.

A reflection on last year at ISPOR Amsterdam:

ISPOR 17th Annual European Congress, Amsterdam, The Netherlands:

- Over 4,800 attendees
- 80 countries represented
- Over 1,950 presentations

"As ever, the ISPOR conference has been very useful both as a learning and sharing of knowledge opportunity and also as an opportunity to network within the industry."

~ ISPOR 17th Annual European Congress attendee (Source: Online Congress Evaluation)

Promotional Opportunities

EXHIBIT

Register now! Over 4800 attendees in 2014!

Present your products and services to congress delegates representing various sectors in the field of health economics and outcomes research.

Benefits to Exhibitors: Listing & $\frac{1}{4}$ page advertisement on the ISPOR website, in the Program & Schedule of Events, and in the meeting app \cdot One complimentary registration per exhibit space \cdot Pre-registrant mailing labels

ADVERTISE

Advertise in the Program & Schedule of Events! Advertising Deadline: 1 September 2015

SPONSOR

Increase your visibility! Give your company increased prominence!

Benefits to Sponsors are based on level of sponsorship and include the following: Recognition in all 3 Plenary Sessions · Event signage · Preference during the booth allocation process · Listing & ¼ page advertisement on the ISPOR website, in the Program & Schedule of Events, and in the meeting app · Complimentary registration(s) based on sponsorship level

Registration Fees

For registration information: www.ispor.org

Early registration deadline: 15 September 2015