



ISPOR 13th Annual European Congress
November 6 – 9, 2010
Prague Congress Centre, Prague, Czech Republic

i3 Innovus ISPOR Contributions

Issue Panel

IP11 ECONOMIC EVALUATION OF NEW CANCER TECHNOLOGIES: IS TRADING UNCERTAINTY FOR LAUNCH TIME WORTH IT?

Moderator: **Joakim Ramsberg PhD**, Director, i3 Innovus, Stockholm, Sweden

Panelists: **Michael Drummond PhD**, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK; **Björn Wettermark PhD**, Pharmacist and Senior Researcher, Center for Pharmaceutical Policy, Stockholm County Council, Stockholm, Sweden; **Josephine Sollano PhD**, Senior Director and Team Leader, Global Outcomes Research, Oncology Business Unit, Pfizer, New York, NY, USA

Workshop

W12: RELATIVE EFFICACY: THE POSSIBLE NEW FRONTIER?

Discussion Leaders: **Monique Martin MBA, MSc**, Vice President, UK Operations, i3 Innovus, Uxbridge, Middlesex, UK; **Benedikte Lensberg MSc**, Project Leader, HEOR Uxbridge, i3 Innovus, Uxbridge, Middlesex, UK; **Michael Drummond PhD**, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK

Purpose: To discuss the implications of relative efficacy for manufacturers and HTA agencies

Description: Currently, relative efficacy (and to some extent effectiveness) is evaluated by third party payers as part of the decision-making process leading to reimbursement (or not) of new medicines. Often, the decisions are based on relative cost-effectiveness. Marketing authorisations on the other hand have traditionally been given on the basis of safety, efficacy and quality relative to no treatment. Recently, European stakeholders have highlighted the need for an improved interaction between payers and regulators, as well as between individual Member States, and questions have been raised about whether relative efficacy should be evaluated as part of the drug licensing process. Relative efficacy involves the analysis of information on how a new drug compares to the gold standard available at launch, which would be obtained by conducting head-to-head trials. This possible new initiative raises many questions, one of the most important being how to establish which gold standard should be included when there are differences between countries. Requirements for establishing relative efficacy to gain reimbursement would present significant challenges to manufacturers who would have to re-think their market access strategies. On the other hand having richer data available at launch could improve, manufacturers' chances for reimbursement. This workshop in three parts would first explain the concept of relative efficacy (not to be confused with relative effectiveness) and would then point out the potential short-comings of relative efficacy. The final section will deal with the possible advantages of this initiative from the perspective of the regulators, companies and technology assessment agencies. Audience participation will be ensured through the conduct of an exercise where a case would be presented and audience solutions solicited.



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Podiums

AD2 THE SOCIETAL BURDEN OF POOR PERSISTENCE TO TREATMENT OF OSTEOPOROSIS IN SWEDEN

Landfeldt E¹, Lundkvist J², Strom O¹

¹i3 Innovus, Stockholm, Sweden, ²Amgen, Stockholm, Sweden

B11 ANALYZING OVERALL SURVIVAL IN RANDOMIZED CONTROLLED TRIALS WITH CROSS-OVER

Jonsson L¹, Sandin R², Ekman M¹, Ramsberg J¹, Charbonneau C³, Huang X⁴, Jonsson B⁵, Weinstein MC⁶, Drummond M⁷

¹i3 Innovus, Stockholm, Sweden, ²Pfizer Oncology, Sollentuna, Stockholm, Sweden, ³Pfizer, Inc., New York, NY, USA, ⁴Pfizer Oncology, La Jolla, CA, USA, ⁵Stockholm School of Economics, Stockholm, Sweden, ⁶Harvard School of Public Health, Boston, MA, USA, ⁷University of York, York, UK

Short Course

RETROSPECTIVE DATABASE ANALYSIS

Faculty: William H. Crown PhD, President, i3 Innovus, Waltham, MA, USA

Course Description: Large administrative claims databases provide a unique opportunity to examine retrospectively the effects of drug use on clinical and economic outcomes in "real world" settings. This course will cover a discussion of the *ISPOR Checklist for Retrospective Database Studies - Report of the ISPOR Task Force on Retrospective Databases* and selected topics related to estimators and sampling distributions, properties of sampling distributions (unbiasedness, efficiency, mean square error), and ordinary least squares (OLS) regression. OLS model assumptions and the implications of violations (e.g., heteroscedasticity, multicollinearity, autocorrelation) will also be discussed. More complex topics beginning with the problem of endogeneity, identification, instrumental variables, sample selection models, and propensity score models, maximum likelihood methods and the estimation of limited dependent variables models including logit, multinomial logit, count models, and survival models will be discussed. *This course will assume participants have knowledge of statistical methods through OLS regression and experience in the analysis of administrative claims databases. This course is recommended as a precursor to the short course "[Applications in Using Large Databases in Europe](#)"*

Posters

PCN13 EFFECT OF ZOLEDRONIC ACID AND PAMIDRONATE ON SKELETAL-RELATED EVENTS AND MORTALITY IN WOMEN WITH BONE METASTASES FROM BREAST CANCER IN A MANAGED CARE PLAN: A RETROSPECTIVE DATABASE ANALYSIS

Henk HJ¹, Kaura S²

¹i3 Innovus, Eden Prairie, MN, USA, ²Novartis Pharmaceuticals Corporation, Florham Park, NJ, USA

PCN14 CLINICAL CONSEQUENCES OF PRIMARY PROPHYLAXIS WITH PEGFILGRASTIM VERSUS FILGRASTIM FOR THE PREVENTION OF FEBRILE NEUTROPENIA IN NON-HODGKIN LYMPHOMA AND STAGE II BREAST CANCER PATIENTS IN GERMANY

Ozer-Deniz S¹, **Taylor DC**¹, **Hill G**¹, **Skornicki M**¹, Danel A², Kunz E³

¹i3 Innovus, Medford, MA, USA, ²Amgen Inc., Zug, Switzerland, ³Amgen (Europe) GmbH, München, Germany

PCN17 NO CONCLUSIVE EVIDENCE FROM RANDOMISED CONTROLLED TRIALS (RCTS) FOR IMPROVED SURVIVAL WITH SECOND-LINE TREATMENT OPTIONS, IN PATIENTS WITH METASTATIC HORMONE-REFRACTORY PROSTATE CANCER (MHRPC) PREVIOUSLY TREATED WITH DOCETAXEL

Mason M¹, Freemantle N², Parnaby A³, **Högberg D**⁴

¹Cardiff Medical School, Cardiff, UK, ²University of Birmingham, Birmingham, UK, ³Sanofi-Aventis, Vitry-sur-Seine, France, ⁴i3 Innovus, Stockholm, Sweden

PCN18 RETROSPECTIVE DATABASE ANALYSIS OF THE EFFECT OF ZOLEDRONIC ACID ON SKELETAL-RELATED EVENTS IN MEN WITH PROSTATE CANCER AND BONE METASTASES

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PCN29 EPIDEMIOLOGY AND HEALTH CARE UTILIZATION FOR RESECTED SQUAMOUS CELL CARCINOMA OF HEAD AND NECK (SCCHN) IN SOUTH KOREA

Kim K¹, Amonkar M², Lykopoulos K³, **Kasteng F**¹, **Högberg D**¹

¹i3 Innovus, Stockholm, Stockholm, Sweden, ²GlaxoSmithKline, Philadelphia, PA, USA, ³GlaxoSmithKline, London, London, UK

PCN45 DIFFERENCES IN HEALTH CARE COSTS FOR PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER (CRPC) TREATED BY ONCOLOGISTS OR UROLOGISTS

Engel-Nitz NM¹, Alemayehu B², Nathan F², Parry D³, **Kulakodlu M**¹

¹i3 Innovus, Eden Prairie, MN, USA, ²AstraZeneca, Wilmington, DE, USA, ³AstraZeneca, Macclesfield, Cheshire, UK

PCN68 COST-EFFECTIVENESS OF PRIMARY PROPHYLAXIS WITH PEGFILGRASTIM VERSUS FILGRASTIM FOR THE PREVENTION OF FEBRILE NEUTROPENIA IN NON-HODGKIN LYMPHOMA AND STAGE II BREAST CANCER PATIENTS IN GERMANY

Taylor DC¹, **Ozer-Deniz S**¹, **Hill G**¹, **Skornicki M**¹, Danel A², Kunz E³

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PCN83 A COST-EFFECTIVENESS ANALYSIS (CEA) FOR DENOSUMAB, A FULLY HUMAN MONOCLONAL ANTIBODY FOR CANCER-TREATMENT INDUCED BONE LOSS (CTIBL) IN NON-METASTATIC PROSTATE CANCER (PRCA): A SWEDISH PERSPECTIVE

Shroff S¹, Martin M¹, Kearney M², Lothgren M², Bracco A²

¹i3 Innovus, Uxbridge, Middlesex, UK, ²Amgen (Europe) GmbH, Zug, Switzerland

PCN99 COST-EFFECTIVENESS OF IMATINIB AS ADJUVANT TREATMENT FOR RESECTED GASTROINTESTINAL STROMAL TUMORS (GIST) VERSUS BEST SUPPORTIVE CARE: CANADIAN PERSPECTIVE

El Ouagari K¹, **Pawar V²**, Coombs J³, **Rubin J²**

¹Novartis Pharmaceuticals Canada, Dorval, QC, Canada, ²i3 Innovus, Medford, MA, USA, ³Novartis, Florham Park, NJ, USA

PCN139 A REVIEW OF DATA COLLECTED ON NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS IN CANCER REGISTRIES, DATABASES, RETROSPECTIVE AND NON-RANDOMIZED PROSPECTIVE STUDIES

De Geer A¹, Eriksson J¹, Finnern HW²

¹i3 Innovus, Stockholm, Sweden, ²Boehringer Ingelheim GmbH, Ingelheim, Germany

PCN162 EXTRAPOLATION IN TRIAL-BASED COST-EFFECTIVENESS MODELLING: IN SEARCH OF A STANDARD

Ekman M¹, Charbonneau C², **Ramsberg J¹**, **Jonsson L¹**, Sandin R³, **Jonsson B⁴**, **Drummond M⁵**, **Weinstein MC⁶**

¹i3 Innovus, Stockholm, Sweden, ²Pfizer, Inc, New York, NY, USA, ³Pfizer Oncology, Sollentuna, Stockholm, Sweden, ⁴Stockholm School of Economics, Stockholm, Sweden, ⁵University of York, York, UK, ⁶Harvard School of Public Health, Boston, MA, USA

PDB64 TREATMENT PERSISTENCE AMONG PATIENTS INITIATING INSULIN THERAPY WITH INSULIN DETEMIR IN A FLEXPEN® VERSUS NPH INSULIN IN A VIAL. RETROSPECTIVE DATABASE ANALYSIS BASED ON A LARGE US MANAGED CARE ORGANIZATION

Conner C¹, **Buysman E²**, **Liu F²**, Aagren M³, Bouchard J⁴

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PDB87 STANDARDS FOR THE ASSESSMENT OF ANTIDIABETIC DRUGS – THE IQWIG PERSPECTIVE

Schweikert B¹, John J², **Ringborg A³**, Erhardt W⁴, Bleckmann A⁵, Neubauer AS⁴

¹i3 Innovus, Aschheim, Germany, ²Helmholtz Zentrum München, Neuherberg, Germany, ³i3 Innovus, Stockholm, Sweden, ⁴Bristol-Myers Squibb, München, Germany, ⁵AstraZeneca, Wedel, Germany

PCV75 CANADIAN COST-EFFECTIVENESS ANALYSIS OF DRONEDARONE VERSUS OTHER ANTI-ARRHYTHMIC DRUGS IN PATIENTS WITH PAROXYSMAL AND PERSISTENT ATRIAL FIBRILLATION

Nilsson J¹, Åkerborg Ö¹, Lindgren P¹, Bascle S²

¹i3 Innovus, Stockholm, Sweden, ²Sanofi-Aventis, Paris, Paris, France



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PIH22 EVALUATING THE COST-EFFECTIVENESS OF CERVICAL CANCER SCREENING AND HUMAN PAPILLOMAVIRUS VACCINATION STRATEGIES USING A MATHEMATICAL MODEL

Taylor DC¹, **Pawar V**¹, **Gilmore K**¹, **Sanon M**¹, Kruzikas D², **Kohli M**³, Arondekar B⁴, Demarteau N⁵, **Weinstein M**⁶

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PIH34 CONTENT VALIDITY OF THE BENIGN PROSTATIC HYPERPLASIA IMPACT INDEX (BII): RESULTS FROM CONCEPT ELICITATION AND COGNITIVE INTERVIEWS

Naegeli A¹, Martin ML², **Kingery LR**³, Viktrup L¹

¹Eli Lilly & Company, Indianapolis, IN, USA, ²Health Research Associates, Inc, Seattle, WA, USA, ³i3 Research, Basking Ridge, NJ, USA

PND34 A PSYCHOMETRIC EVALUATION OF THE REVISED SCOPA DIARY CARD IN PARKINSON'S DISEASE PATIENTS

Buck PO¹, Castelli-Haley J¹, White RE¹, **Rendas-Baum R**², **White MK**²

¹Teva Neuroscience, Kansas City, MO, USA, ²QualityMetric Incorporated, Lincoln, RI, USA

PND36 HEALTH STATUS COMPARISON BETWEEN STABLE PARKINSON'S DISEASE PATIENTS AND THOSE EXPERIENCING OFF-TIME

Buck PO¹, White RE¹, Castelli-Haley J¹, **Rendas-Baum R**², **White MK**²

¹Teva Neuroscience, Kansas City, MO, USA, ²QualityMetric Incorporated, Lincoln, RI, USA

PSS11 THE COST-EFFECTIVENESS OF A NEW GEL FORMULATION OF CALCIPOTRIOL/BETAMETHASONE DIPROPIONATE FOR THE TREATMENT OF SCALP PSORIASIS IN NORWAY

Holm MV¹, **Ekman M**², Rytrov J³

¹LEO Pharma, Ballerup, Denmark, ²i3 Innovus, Stockholm, Sweden, ³LEO Pharma, Marlow, UK

PIN2 ESTIMATED IMPACT OF SUSTAINED VIROLOGICAL RESPONSE (SVR) ON LIFE EXPECTANCY, QUALITY-ADJUSTED LIFE-YEARS (QALYS) AND LIFETIME COSTS IN CHRONIC HEPATITIS C (CHC) PATIENTS

Cure S¹, **Bianic F**¹, **Cawston H**¹, **Dartois L**¹, Zhang H²

¹i3 Innovus, Uxbridge, Middlesex, UK, ²Johnson & Johnson Pharmaceutical Services, LLC, Raritan, NJ, USA

PIN38 AN ECONOMIC EVALUATION OF THE PEDIATRIC VACCINATION SCHEDULE IN THE UNITED STATES

Clements KM¹, Misurski DA², Miller J³, **Skornicki ME**¹, **Hill GJ**¹, **McGarry L**¹

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PIN42 THE COST-EFFECTIVENESS OF 13-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV13) COMPARED WITH 10-VALENT PNEUMOCOCCAL CONJUGATE VACCINE (PCV10) IN TAIWAN

Chang CJ¹, Wu DBS², Wu CL¹, Strutton D³, Hwang S³, Huang VWH⁴, **Rubin J**⁵, **Gilmore K**⁵
¹Chang Gung University, Taoyuan, Taiwan, ²National Yang-Ming University, Taipei, Taiwan, ³Pfizer Limited, Collegeville, PA, USA, ⁴Pfizer Limited, Taipei, Taiwan, ⁵i3 Innovus, Medford, MA, USA

PMH21 SOCIETAL COSTS OF BIPOLAR DISORDER – THE CASE OF SWEDEN

Ekman M¹, Granström O², Omerov S³, Jacob J², Landén M⁴
¹i3 Innovus, Stockholm, Sweden, ²AstraZeneca Nordic MC, Södertälje, Sweden, ³Northern Stockholm Psychiatry, Stockholm, Sweden, ⁴Gothenburg University, Göteborg, Sweden

PSY51 STATED PREFERENCES OF PHYSICIANS AND CHRONIC PAIN SUFFERERS IN THE USE OF CLASSICAL STRONG OPIOIDS

Chancellor J¹, **Martin M**², Liedgens H³, Baker MG⁴, Müller-Schwefe GH⁵
¹Chancellor Health Economics Ltd, Beaconsfield, Buckinghamshire, UK, ²i3 Innovus, Uxbridge, Middlesex, UK, ³Gruenthal GmbH, Aachen, Germany, ⁴European Federation of Neurological Associations, Helensburgh, UK, ⁵German Pain Association, Göppingen, Germany

PUK7 THE PHARMACY BUDGET IMPACT OF EXTENDING REIMBURSEMENT OF LANTHANUM CARBONATE TO TREATMENT OF HYPERPHOSPHATEMIA (>1.78MMOL/L) IN PATIENTS WITH CHRONIC KIDNEY DISEASE PRE-DIALYSIS IN FRANCE AND THE UNITED KINGDOM

Campbell J¹, **Tao CY**¹, Keith MS², **Leahy KJ**¹, Russo L²
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Principal Consultant Contributions

Plenary Sessions

ASSESSMENT OF HEALTH TECHNOLOGY IN EUROPE: TAKING STOCK OF THE INEFFICIENCIES

Moderator/Speaker: **Bengt Jonsson PhD**, Professor of Health Economics, Centre for Health Economics, Stockholm School of Economics, Stockholm, Sweden.

KEY TRENDS AND DEVELOPMENTS IN HEALTH TECHNOLOGY DECISION-MAKING IN EUROPE

Speaker: Michael Drummond PhD, Professor of Health Economics, Centre for Health Economics, University of York, Heslington, York, UK.

Workshop

W20: MAXIMUM ACCEPTABLE RISK: ALTERNATIVE MEASURES FOR QUANTIFYING PATIENTS' TOLERANCE FOR THERAPEUTIC RISKS

Discussion Leaders: A. Brett Hauber PhD, Global Head, Health Preference Assessment & Market Access, RTI Health Solutions, Research Triangle Park, NC, USA; F. Reed Johnson PhD, Distinguished Fellow and Principal Economist, RTI Health Solutions, Research Triangle Park, NC, USA; Axel Christian Mühlbacher PhD, Professor for Health Economics, IGM Institute Health Economics and Health Care Management, HS Neubrandenburg, Neubrandenburg, Germany; **Deborah Marshall PhD**, Canada Research Chair, Health Services and Systems Research, University of Calgary, Calgary, AB, Canada

Purpose: The purpose of this workshop is to review and appraise three alternative methods for estimating patients' tolerance for therapeutic risks.

Description: Regulators in the EU and US currently are evaluating alternative approaches to quantitative benefit-risk assessments of pharmaceutical products. One approach under consideration is to elicit patients' stated risk tolerance directly. There are three possible methods for quantifying patient preferences for benefit-risk tradeoffs: traditional health-state utility approaches, contingent-valuation using bidding games, and conjoint analysis. The workshop will include a presentation to describe the conceptual framework, practical implementation, and empirical examples of each of these methods. The workshop also will include an interactive segment in which audience members will answer survey questions based on a hypothetical case study. The discussion leaders will then debrief participants on their experience and elicit critical assessments of the validity and likely acceptability of the data produced by each method.