was the primary endpoint, and compared the assessments. RESULTS: Guidance from regulators indicates the suitability of trials and endpoints on the cancer type and stage, seen in assessments of atabrine and etonabine in non-small cell lung cancer and bevacizumab in ovarian cancer. FDA and EMA approvals were based on FFS data. However, the TC in France awarded ASMR IV for etonabine and bevacizumab and ASMR V for atabrine. METABASE is a library based on additional interim OS data and a patient access scheme, bevacizumab was not approved because of uncertainty in translating PFS gain to OS. CONCLUSIONS: FFS is in the pipeline for a number of agents, which incentivizes industry to provide patient access schemes. However, the results in stakeholder perspectives and evidentiary requirements may mean that products approved on the basis of FFS data face delays in HTA or protracted pricing negotiations, or are rejected for reimbursement. FFS as an endpoint allows shorter trials, efficiency is improved, and fewer patients are exposed to an investigational drug. The limitations associated with FFS as an endpoint are largely manageable. Thus, the value and relevance of FFS needs to be recognized consistently across HTA agencies, and approaches harmonized between HTA agencies and regulators.

PRM15 STAKEHOLDER VIEWS ON THE ACCEPTABILITY OF REAL-WORLD EVIDENCE FOR INFORMING TRIAL DESIGN AND ASSESSMENT OF RELATIVE EFFECTIVENESS OF NEW MEDICINES

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OBJECTIVES: To elicit a comprehensive stakeholder view on the acceptability of using real-world evidence (RWE) for informing trial design and establishing relative effectiveness (RE) of new medicines in regulatory and HTA assessments. METHODS: IMI GetRecomm (SOLAR) is facilitating stakeholder dialogue on the use of RWE in clinical trial design, for RWE through case studies which focus on RE issues in several disease areas. In a series of pilot workshops, stakeholders considered challenges in establishing the RE of multiple sclerosis treatments and alternative solutions for reducing decision-making uncertainty. To elicit these challenges: participants provided views on the usefulness and acceptability of solutions and the potential impact on regulatory and reimbursement decision making. RESULTS: Three approaches were proposed: 1) supplementing trial results with large data analysis (BMS), 2) incorporating external evidence for supportive decision-making (GSK), and 3) using real-world data to inform evidence synthesis for new REs (GSK). The consensus was that RWE in NMA to support simulations informing trial designs; 3) using risk equations derived from RWE to inform risk stratified trial designs. Stakeholders cautiously welcomed the proposals as additional options for reducing decision-making uncertainty, raising the key issue of potential biases that could be introduced by including RWE in these ways. The inclusion of RWE would most likely be considered as supportive of or detrimental to an existing RE if the bias introduced were put in place to mitigate biases commonly associated with non-interventional data. CONCLUSIONS: For the use of RWE to become more acceptable by decision makers, standard methods for data synthesis should be developed, as well as guidelines to ensure transparency in selection of data sources and data synthesis. The GetRecomm platform provides a safe harbour for stakeholders to discuss the potential use of RWE for decision making, and further work is ongoing to develop methods for the ‘early use of RWE and to foster dialogue between stakeholders.

PRM16 KNOWLEDGE AND AWARENESS OF BREAST CANCER AMONG YOUNG WOMEN LIVING IN SOUTH INDIA

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OBJECTIVES: Objective of this study was to provide a baseline against which to monitor trends in breast cancer awareness and the effect of interventions to promote breast cancer awareness. METHODS: A cross sectional house hold survey was conducted on a total of 18-40 age group of 18-40 in urban and rural areas of South India using a validated questionnaire. RESULTS: A total of 99% respondents knew that breast cancer is the leading cancer with a mean knowledge score of 73.7±15.1 for urban and 47±13.9% for rural women. Sources of information for their knowledge were mainly health professionals/workers (98.2%), friends/neighbors (83.5%), TV/Radio (76.0%) and printed materials (60.2%). Rural women had significantly less awareness compared to urban women. Majority of the respondents knew the risk factors of breast cancer aging (69%), nulliparity (56.4%), delivery at more than 30 years old (46%), shorter duration of breast feeding (72%), contraceptive pills (46%), obesity (80.0%), big breast (81%), hormone replacement therapy (HRT) (54.4%), menopause after the age of 52 (20%) and breast feeding (72.0%). A total of 99% of urban respondents believed that breast cancer is preventable, while 65.6% of rural respondents did not believe that breast cancer is preventable. The most common disposing factors and direct effects of post-stroke spasticity (PSS) also involve high management costs in terms of healthcare resources and case-control designs are required for establishing such differences. In ‘The Health Improvement Network’ (THIN) database, such a study was difficult to provide reliable estimates since the prevalence of post-stroke spasticity was found to be substantially below the most conservative previously reported estimates. The objective of this study was to use predictive analysis techniques to determine if there were a substantial number of potentially under-recorded patients with PSS. METHODS: This study used retrospective data from adult patients with a diagnostic code for stroke between 2007 and 2011 from 118 practices in THIN. The data were stratified by sex and regional and validated data-driven algorithm using machine techniques and potential predictors; and 2) a clinician-trained algorithm based on the review of 200 stroke cases by 6 independent neurologists. The final algorithm was compared with the clinician algorithm used to identify PSS cases. RESULTS: In THIN data, 45,613 stroke events were identified, with 660 having a diagnosis FSS. A data-driven algorithm using Random Forest showed better prediction performance than the clinician-trained algorithm, with higher sensitivity and only marginally lower specificity. Overall sensitivity was 84% and 72%, respectively. The data-driven algorithm predicted an additional 3,912 records consistent with patients developing spasticity in the 12 months following a stroke. CONCLUSIONS: Using machine learning techniques, additional unrecorded post-stroke spasticity patients were identified, increasing the condition’s prevalence.

PRM19 MACHINE LEARNING FOR IDENTIFYING POTENTIALLY UNDIAGNOSED POST-STROKE SPASTICITY PATIENTS IN UNITED KINGDOM

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OBJECTIVES: Spasticity is one of the well-recognised complications of stroke which may give rise to pain and limit patients’ ability to perform daily activities. The predisposing factors and direct effects of post-stroke spasticity (PSS) also involve high management costs in terms of healthcare resources and case-control designs are required for establishing such differences. In ‘The Health Improvement Network’ (THIN) database, such a study was difficult to provide reliable estimates since the prevalence of post-stroke spasticity was found to be substantially below the most conservative previously reported estimates. The objective of this study was to use predictive analysis techniques to determine if there were a substantial number of potentially under-recorded patients with PSS. METHODS: This study used retrospective data from adult patients with a diagnostic code for stroke between 2007 and 2011 from 118 practices in THIN. The data were stratified by sex and regional and validated data-driven algorithm using machine techniques and potential predictors; and 2) a clinician-trained algorithm based on the review of 200 stroke cases by 6 independent neurologists. The final algorithm was compared with the clinician algorithm used to identify PSS cases. RESULTS: In THIN data, 45,613 stroke events were identified, with 660 having a diagnosis FSS. A data-driven algorithm using Random Forest showed better prediction performance than the clinician-trained algorithm, with higher sensitivity and only marginally lower specificity. Overall sensitivity was 84% and 72%, respectively. The data-driven algorithm predicted an additional 3,912 records consistent with patients developing spasticity in the 12 months following a stroke. CONCLUSIONS: Using machine learning techniques, additional unrecorded post-stroke spasticity patients were identified, increasing the condition’s prevalence.

PRM17 ANALYSIS OF EVIDENCE DATA ABOUT ADDING SUCINIC ACID TO THE VARIOUS MEDICINES

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OBJECTIVES: Succinic acid as endogenous metabolite, has a wide range of application in medical practice. We conducted a review research on the development of new medicines based on succinic acid, ascorbic acid and rutin for the prevention and treatment of influenza. A systematic review was carried out to perform a qualitative assessment of succinic acid adding in the various medicines and to determine of their pharmacological action. MEDLINE®, EMBASE®, Scopus, Cochrane Library databases and clinical trials registers between 1996 and Jun 2015 were performed. To analyze the RCT were selected and Review on the Study of the pharmacological action of drugs, which in clinical trials with placebo or active control. However, the results of relevance RCT are grouped as follows: 1) lower antiviral therapy - 7 RCT (2003-2013 years), 2) lower iron absorption in the gastrointestinal tract - 6 RCT (1966-1974), 3) hypoglycemic - 4 RCT (2013-2014 years). One RCT proves the efficiency of succinic acid used in gastroenterology (a combination with omeprazole, 2012), depres- sion (2013), in transplantation (1993) at menopause (2008), renal failure (2013), to improve body temperature during surgery (2007). Analysis of Review opens the new perspective of the use of succinic acid as a vitamin in Ukraine. CONCLUSIONS: A comprehensive overview of these studies estimated the evidence of succinic acid addition of the drugs. Succinic acid as endogenous metabo- lite, is a part of drugs of different pharmacological actions. These clinical trial results have been retrieved and give the possibility to develop new drugs with succinic acid also in Ukraine.
in THIn from 2% to 13%. This work shows the potential for under-reporting of PSS in primary care data, and provides a method for improved identification of cases and control records for future studies.

**PM21**

**PANGAEA 2.0: STATE OF THE ART MULTIPLE SCLEROSIS PATIENT MANAGEMENT IN DAILY CLINICAL PRACTICE. A NEW 3-YEAR OBSERVATIONAL STUDY OF PATIENTS RECEIVING FINGOLIMOD**

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**OBJECTIVES:** The therapeutic options for Multiple Sclerosis (MS) improved over the past years with the approval of new substances. Therapeutic optimization must thus be taken into account an individualized assessment of clinical and imaging disease activity, treatment response as well as identifying early risk factors for treatment failure. This study aims to assess the impact of introducing phase III trials on the treatment, to assess the utility of a tool that helps to identify patients with ongoing disease activity 2. The systematic collection of a broader set of functional domains to explore their potential to be used as a predictive measure of future disease activity or treatment response. 3. Evaluate the clinical impact of the therapy. Scores provided by relapse activity, disability progression, MRI activity and change in volume 4. Assess the therapeutic effectiveness of switching to fingolimod if the patients are assessed to be failing their current first line therapy. METHODS: 1500 patients are planned to be included in this observational study. All patients with active disease as defined by Lublin et al., 2014, under a first line disease-modifying treatment (DMT) will be enrolled. This enables the PH assumption to be formally tested, and a time ratio (TR) or “secondary” outcome in 10 studies (22%) had OS as primary endpoint (though only 3 of them reached statistical significance), in over 37 (41%) OS was grouped with other outcomes to form a composite endpoint. In 55 studies (61%) overall survival was a secondary outcome. Quality of life was a “secondary” outcome in 10 studies. CONCLUSIONS: Although OS is the gold standard in cancer therapy, grouped outcomes are often used in cancer outcomes, such as progression-free survival (PFS) or paracancerous indicators of disease activity are more frequently used and may be good predictors. Intermediate outcomes require smaller samples sizes and less follow-up. They are usually used to predict OS, or, indeed, quality of life benefits more accurately. Only in the most aggressive forms of cancer is patient survival used as OS or survival justified as the primary endpoint.

**PM22**

**TIME RATIOS OR HAZARD RATIOS: ACCELERATING TOWARD A NEW APPROACH?**

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**OBJECTIVES:** Syntheses of time-to-event data often rely on published hazard ratios (HR) therefore assuming proportional hazards (PH). Methods now exist to reconcile the event hazard whilst also representing an acceleration in time-to-event, the hazard ratio for treatment vs. control. TRs act on the log-hazard scale representing the ratio of hazards for treatment vs. control. A HR < 1 represents a decrease in hazard. In clinical practice, the greatest evidence is found in terms of: scale, underlying assumptions, interpretation, availability in published literature and derivation. RESULTS: HRs act on the log-hazard scale representing the ratio of hazards for treatment vs. control. TRs act on the log-failure time scale, representing the ratio of failure times for treatment vs. control. A HR < 1 represents a decrease in failure. CONCLUSIONS: PANGAEA 2.0 will give important insights on the predictive value of proposed treatment algorithms like the Lublin criteria and the modified Rio Score when tried in real world patients. We aim to validate the results of the real-world use and evaluate the benefit of a collection of a broad range of outcome parameter based on functional domains from a patient and physician perspective on therapy decisions.

**PM23**

**OUTCOMES USED IN CLINICAL STUDIES IN ADULT HEMATOLOGY: TEN YEARS OF PUBLICATIONS IN PUMED**

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**OBJECTIVE:** To determine which clinical outcomes, both “soft” and “hard”, are currently assessed in phase III trials in hematological malignancies with what proportion of them use overall survival (OS) as the primary outcome. METHODS: Through a search in PubMed, we identified and analyzed all randomized clinical trials published in the last 10 years, for new treatments in adults. RESULTS: Characteristics of the studies are shown in Table 1. CONCLUSIONS: OS is the gold standard in cancer therapy, grouped outcomes are often used in cancer outcomes, such as progression-free survival (PFS) or paracancerous indicators of disease activity are more frequently used and may be good predictors. Intermediate outcomes require smaller sample sizes and less follow-up. They are usually used to predict OS, or, indeed, quality of life benefits more accurately. Only in the most aggressive forms of cancer is patient survival used as OS or survival justified as the primary endpoint.

**PM24**

**PATIENT VERSUS GENERAL POPULATION HEALTH STATE VALUATIONS: A CASE STUDY OF LOW BACK PAIN**

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**OBJECTIVES:** The objectives of this study were: 1) to compare low back pain (LBP) patient valuations with general population valuations for more broader aspects of health-related quality of life as measured by the EQ-5D-3L, impact LBP patient valuations, and 3) to explore the implications of the choice of valuation method for cost-utility analyses (CUAs). METHODS: Data of 483 LBP patients and most studied disease was multiple myeloma, with 29 studies, followed by non-Hodgkin lymphoma with 26. The others were acute myeloid leukemia 12, chronic lymphocytic leukemia 10, chronic myeloid leukemia 8, myelodysplastic syndromes 3 and Hodgkin lymphoma 2. The 90 studies had a total of 108 “primary” and 252 “secondary” outcomes; 20 studies (23%) had OS as primary endpoint (though only 3 of them reached statistical significance), in over 37 (41%) OS was grouped with other outcomes to form a composite endpoint. In 55 studies (61%) overall survival was a secondary outcome. Quality of life was a “secondary” outcome in 10 studies. CONCLUSIONS: Although OS is the gold standard in cancer therapy, grouped outcomes are often used in cancer outcomes, such as progression-free survival (PFS) or paracancerous indicators of disease activity are more frequently used and may be good predictors. Intermediate outcomes require smaller sample sizes and less follow-up. They are usually used to predict OS, or, indeed, quality of life benefits more accurately. Only in the most aggressive forms of cancer is patient survival used as OS or survival justified as the primary endpoint.

**PM25**

**STOCHASTIC MULTICRITERIA ACCEPTABILITY ANALYSIS IN A BAYESIAN FRAMEWORK**

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**OBJECTIVES:** Stochastic multicriteria acceptability analysis (SMAA) is a powerful tool for health technology benefit-risk assessment when health outcomes are assessed according to multicriteria and both the outcomes and preference weights are subject to uncertainty, in particular with missing weight information. We propose using a Bayesian approach for SMAA to provide an alternative or supplement to the standard SMAA. It can estimate the posterior distributions of decision maker’s preferences on multicriteria weights, had he/she prefer treatment A over B. Given the preference on previous treatments and safety and efficacy profiles, it can also predict the decision maker’s preference on a new treatment. METHODS: The SMAA method was adapted to fit into the Bayesian framework, assuming that the weights follow a Dirichlet prior distribution. A simple Monte-Carlo procedure was developed to conduct the calculations for the two criteria, and Bayesian credible intervals of major measures in standard SMAA were derived. An algorithm was also developed to predict future rankings. The method allows using informative, non-informative or hierarchical priors, and can be extended to other SMAA methods such as that based the prospect theory (SMAA-P). This method is applied to the assessment of