of needed raw data, r can be computed from relative risks, odds ratios, t statistics, F statistics, chi square statistics, standard normal deviate Z statistics, and beta coefficients. In studies reporting p-values only, p-values can be converted to their associated one-tailed standard normal deviate Z values to allow the calculation of r. Before computed r's can be combined, they must be transformed using the Fisher Z transformation in order to normalize their distribution. The weighted and un-weighted Fisher Z transformed r's are then converted back to r's, and the weighted and unweighted mean r's are calculated. Confidence intervals around these estimates show the degree to which they significantly differ from zero. For the un-weighted mean r, the random effects confidence interval is usually preferred. Although such confidence interval tends to be wider, it allows generalization to studies other than those included in the sample. This methodology is demonstrated using a dataset from a systematic review of published scientific literature. The analysis shows how diversely-reported effects sizes can be converted and combined to produce a summary r, which explains the association between specific determinant and outcome variables. Despite the value of correlation r in meta-analysis, it continues to be underused in the synthesis of scientific evidence.

PRM47
DEVELOPMENT OF LOCALLY ADAPTABLE VALUE ARGUMENTS: HOW CAN BUCKETING OF COUNTRIES AT GLOBAL LEVEL HELP MANUFACTURERS?

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Data requirements from reimbursement authorities globally vary greatly due to variation in importance of HTA and levels of acceptable complexity in submitted economic evidence. Often market differences have been addressed by global pharmaceutical companies by developing value arguments that address the most developed reimbursement systems, which then have to be adapted locally, often resulting in the duplication of effort among local affiliates. Placing customer requirements and informal preferences as the starting point of the development of value arguments can increase efficiency and more specifically meet local HTA needs. Methodologies that will support development of locally adaptable value arguments – both value dossiers as well as health economic messages - requires first of all the understanding of local payer needs. Countries requiring submission of economic data can be classified on the basis of commonly required assessment methods – budget impact analysis, cost effectiveness analysis and cost minimisation analysis, as well as the complexity accepted in both submitted clinical and economic evidence. This complexity is in terms of level of complexity of data requirements for Health Economic analysis, technical modelling approach, CE outcome, local/international data preference, preference for comparator, preferred time horizon amongst others. This can be used to divide these countries into buckets with similar requirements. Globally developed value arguments can be developed and adapted to these buckets of countries and their needs. Basing value arguments that are developed globally as mentioned, and then sent to local affiliates to adapt to the specific needs of their HTA system, on the preferences of customers is expected to be crucial to ensure local success for reimbursement.

PRM48
DESIGN AND OPERATIONAL CONSIDERATIONS FOR PRAGMATIC CLINICAL TRIALS TO SUPPORT HEOR EVALUATIONS

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Unlike randomized controlled trials (RCTs), pragmatic clinical trials (PCTs) measure the relative benefits of competing treatments in actual practice, thus, are an important pharmacoeconomic data source. Depending on the design features, trials can vary in their degree of pragmatism. We undertook a brief review of the literature to highlight specific PCT design considerations that optimize their utility for health economic and outcomes research (HEOR) applications. A broad population and active control groups, typical in PCTs, can help achieve generally representative HEOR assessments and reduce reliance upon indirect comparisons. A minimally restrictive protocol is needed to preserve a naturalistic focus, and for reducing Hawthorne effects. Some control is required, however, to minimize study biases. Randomization to initial treatment choice remains essential to avoid selection bias and confounding, but little control should be exerted on regimen changes so that real-world prescribing patterns (switching, adding, and dropping) patterns and patient behaviors (non-compliance, non-adherence) can be evaluated. In the absence of blinding, ascertainment bias is also a risk; use of objectively measured outcomes that may even be identifiable from medical charts can help. Capturing clinical, resource utilization, safety, preference, and quality of life, outcomes can lead to richer economic models, and better understanding of usual-care treatment decisions. With a broad patient base, it is important to explore subgroup effects, and to prioritize predictive analyses to identify response variation. Beyond a thoughtful study design, key operational elements such as site selection, patient recruitment and retention and ongoing study support are critical to PCT success.

PRM49
TRANSLATION AND LINGUISTIC VALIDATION – METHODOLOGICAL IMPLICATIONS WHEN THE SOURCE MEASURE IS NOT ENGLISH

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The majority of new PRO measures are developed in English, with a small minority developed in other languages. This poses the question of how to translate and linguistically validate measures developed in languages other than English, when the resources are simply not available for translating from the source language (e.g.

Hungarian) into the target language (e.g. Bengali). The URAM Scale assesses functional performance of the hand in patients with Dupuytren's Contracture. It was developed in French and initially translated and linguistically validated into UK English. The methodology employed for this translation was the reverse of a typical English to French translation, whereby the French in-country investigator acted as the project manager and an in-house project manager (qualified in French to English translation) acted as the in-country investigator. The translation into English required consultation with the developer and two issues needed to be resolved in order to develop the UK English version. One item required alternative wording as it mentioned wash mitts, which are very rarely used in the UK, and for another item, two verbs were required to convey the meaning of a single French verb. On completion of the translation, the UK English version was then used as a source version for the translation of the URAM Scale into several other European languages. During this process the translators were asked to work from the English version but to also consider the relevance of the original French wording for the two items that required a change in English. For example, in countries where wash mitts are used, this wording was retained instead of the new English wording which used 'flannel'. This experience highlights the importance of always considering the original development language when translating a measure using a generated English version as the source.

POSTER SESSION III:
DISEASE-SPECIFIC STUDIES

Cancer – Clinical Outcomes Studies

PCN1
CHEMOTHERAPY INDUCED NAUSEA AND VOMITING EVENT RATE AMONG PATIENTS WITH CANCER TREATED WITH HIGHLY OR MODERATELY EMETOGENIC CHEMOTHERAPY AND INITIATED ON PALONOSETRON VERSUS OTHER 5-HT3-RECEPTOR ANTAGONIST ANTI-EMETIC PROPHYLAXIS IN A HOSPITAL OUTPATIENT SETTING

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OBJECTIVES: To assess the rate of chemotherapy induced nausea and vomiting (CINV) associated with palonosetron (a 5-hydroxy tryptamine$_3$-receptor antagonist [5-HT$_3$-RA]) initiation versus other 5-HT$_3$-RAs among patients with cancer on highly [HEC] or moderately emetogenic chemotherapy (CT) [MEC] treatment in a hospital outpatient setting. **METHODS:** Patients with a cancer diagnosis initiating HEC or MEC and anti-emetic prophylaxis with palonosetron (Group 1) or other 5-HT$_3$-RAs (Group 2) for the first time (index date) between 4/1/2007 – 3/31/2009 were identified from the Premier Perspective comparative database. Inclusion criteria were patients aged ≥ 18 years with no evidence of nausea and vomiting or use of HEC/MEC or anti-emetic medication in the 6-month pre-index date period, and with 36-consecutive months of hospital data. Follow-up time was first of eight CT cycles (a cycle was the unit of analysis) or six months post-index date. A negative binomial distribution generalized linear multivariate regression model estimating the CINV event rate on CT matched groups in the follow-up period was developed after controlling for demographic and clinical variables. **RESULTS:** Of 6418 identified patients, 1522 (23.7%) initiated palonosetron. Group 1 patients comprised of less African Americans (8.7% vs. 14.2%) and more Hispanics (5.7% vs. 4.5%); p<0.0001, more patients on HEC [50.5% vs. 41.5%; p<0.0001, and more non-colon gastrointestinal (10.3% vs. 6.3%) and breast cancer patients (19.5% vs. 16.8%); p<0.0001. In the follow-up period, the number of unadjusted CINV events between the matched groups was lower for Group 1 [6957 vs. 7784; p=0.054] patients. The regression model predicted a significant decrease (12.5%) in the CINV event rate per CT cycle for Group 1 patients versus Group 2 patients; p=0.0044. **CONCLUSIONS:** In this retrospective hospital outpatient study, patients with cancer treated with HEC/MEC and initiated on palonosetron were more likely to experience a significantly lower rate of CINV events versus those initiating other 5-HT3-RAs.

PCN2
SAFETY AND TREATMENT PATTERNS OF ANGIOGENESIS INHIBITORS IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA (MRCC) IN THE UNITED KINGDOM: PRELIMINARY RESULTS OF AN ONGOING CHARTS REVIEW STUDY

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OBJECTIVES: This study evaluated the rates of and reasons for treatment modifications and occurrence of adverse events (AEs) among patients treated with anti-angiogenic agents in UK clinical practice. **METHODS:** Data from medical records were retrospectively reviewed at 3 large UK oncology centers for mRCC patients who were ≥18 years and received sunitinib (N=90) as first-line treatment from January 1, 2005 to October 15, 2010. Proportions of patients with treatment modifications (i.e.: discontinuation, interruption, or dose change) and reasons for modifications were determined. Time to treatment discontinuation and proportion of patients with all grade and grade 3/4 AEs were also determined. Data on clinician assessed response rates was collected. **RESULTS:** Ten percent of patients were cytokine-pretreated. Average daily dose over initial cycle was 31.98 mg; 77.8% of patients started treatment with recommended dosing of 50 mg QD 4/2. Among the 62 patients with available tumor response assessments, 35.5% had an objective response (OR; complete or partial response). A total of 84.4% of patients experienced AEs; 24.4% experienced grade 3/4 AEs. The most commonly reported all grade AEs were diarrhea (35.6%), mucositis/stomatitis (34.4%), and fatigue (26.7%);