both challenges and opportunities for industry. The changes in the DSM-5 criteria may translate into changes for how we go about developing medical products to treat psychiatric disorders, including ADHD. There will need to be an investment in research and education, and sponsors must examine the possibility of developing new endpoints and outcome assessments for use in clinical trials.

**PMR185**

**THE IMPACT OF DSM-5 ON THE DEVELOPMENT OF DRUGS TO TREAT MAJOR DEPRESSIVE DISORDER**

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**OBJECTIVES:** In May 2013, the American Psychiatric Association released the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), a classification system for psychiatric conditions. DSM-5 brings significant changes to many diagnostic categories as compared to the previous edition. The objective of this meta-analysis was to evaluate the changes in the future submission of the endpoint and discuss the impact these changes may have for industry. **METHODS:** A line-by-line review of the DSM-5 and DSM-IV criteria for MDD was undertaken. Significant changes were highlighted and discussed from the point of view of sponsors of all submissions. **RESULTS:** Sponsors are being challenged to tackle new endpoints and outcome assessments for use in clinical trials. A review of the new endpoints and outcome assessments for MDD may translate into changes for how we go about developing medical products to treat MDD.

**PMR186**

**PATIENT NETWORKS AS A DATA SOURCE FOR PATIENT REPORTED OUTCOMES**

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**OBJECTIVES:** To explore the potential of online patient networks (PNs) as a viable source of patient-reported research data. **Methods:** Data were collected for 601 patients who have entered the last few years in different European countries, and as a natural meeting point for chronic patients with a patient engaged with their communities, they represent a promising source of patient reported data. In this original study, we compare the experience with the French PN “Carenity”, and the fact that the test was computer-lead by definition, a Computer Adaptive Test (CAT) was considered the best choice. The authors decided to use a culturally adapted version of CAT Health system, which measures generic health-related quality of life (HRQoL). However, in absence of a calibration for the French population, a selection of the best items was used, using the Spanish calibration as a reference. All participants in the test. A score was estimated for the test using the Spanish parameters, as a rough approximation of the real score. **Results:** Preliminary results from the first week of data collection show 601 patients answered (Women: 404, Men: 140). The most frequent reported pathologies were diabetes, cancer and cardiovascular diseases. **Conclusions:** The PN seems to be a fast way to obtain PRO scores directly from patients. Preliminary results show differences in the expected direction.

**RESEARCH ON METHODS – Statistical Methods**

**PMR187**

**DEFINING THE PROPER METHODOLOGY TO USE IN A DATA-PEEK FOR POWER (DPP)**

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**OBJECTIVES:** Late phase research is conducted outside the RCT setting where there is uncertainty as to how many subjects are needed to find differences between groups. Due to the lack of real-world information (non-RCT) in late phase designs, there are tangible inputs for power calculations. This research defines a bias-free methodology while determining the sample size for the application of a DPP, a study examining the decrease of HbA1c values in two different insulin delivery methods was examined in patients with several comorbidities. Literature examining found patients to be a priori and the DPP was used to determine effect size (ES) and standard deviations (SD) on 30 patients who had been enrolled in each group. The DPP procedure was: 1. Measure the test statistic; 2. Identify the power formula most appropriate to the test statistic; 3. Determine the variables which may influence the endpoint; 4. Follow-up the study and the test statistic; 5. Construct a matrix of possible sample size values; and 5. Select a sample size that is obtainable and answers the research question. **RESULTS:** Data for group A demonstrated a mean reduction of 0.75% ± 0.76% and group B mean reduction of 0.01% ± 0.63%. Exact power analysis showed 113 subjects per group would be needed. A matrix of likely sample size based on these values ranged from 44 to 193 per group. Based on this DPP, a sample of 120 per group was selected as the sample size that would deliver clinically meaningful results. **CONCLUSIONS:** A DPP is useful in late phase data to define appropriate sample size where no data exist. It is important to note that DPP methods do not require significance testing, but the benefit is no need for a correction for multiple comparisons at the time of the final analysis.

**PMR188**

**FASTE: CONNECTIONS – CAN CRITICISMS OF NETWORK META-ANALYSIS IN NICE SUBMISSIONS BE AVOIDED?**

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**OBJECTIVES:** To assess 1) how network meta-analyses (NMAs) included within manufacturer submissions to the National Institute for Health and Care Excellence (NICE) have been criticised by its Evidence Review Groups (ERG); 2) how the use of different frameworks might influence the selection of relevant studies; and 3) the extent to which avoidance might increase the likelihood of a new intervention being approved. **METHODS:** We reviewed the ERG reports of all NICE technology appraisals published since January 2007 to identify those where the manufacturer’s submission included an NMA. Subsequently all criticisms made by the ERG of such analyses were analysed to seek common themes; and assess how often any one type of criticism was associated with a rejection by NICE. **RESULTS:** A total of 181 NICE technology appraisal reports were evaluated. These covered 243 separate interventional options, 83 (34%) of which were drugs for cancer. Overall 37–64% of submissions cited NMAs, of which 43–83% were criticised, with this proportion having increased over time. Avoidable criticisms related to flaws in the systematic review methodology used to identify relevant RCTs for the analysis, inappropriate pooling of data from heterogeneous studies, and use of suboptimal statistical approaches in conducting the NMA. Unavoidable criticisms related to the lack of RCTs available for competitor drugs in the target population. Therefore, no association was found between flaws in the NMA and a decision by NICE not to approve the use of the intervention. Instead, such rejection was associated mainly with a lack of evidence of clinical effectiveness or a target population of patients. **CONCLUSIONS:** Most criticisms of NMAs could be avoided by a more rigorous and transparent approach to conducting and reporting the underlying systematic review and statistical analysis. However, rejection of submissions remains a considerable risk where the underlying evidence is weak.

**PMR189**

**METHODOLOGICAL CHALLENGES IN COMPARING TOPICAL THERAPIES IN DERMATOLOGY IN THE ABSENCE OF HEAD-TO-HEAD STUDIES**

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**OBJECTIVES:** German HTA agency requires evidence about the additional benefit of a new pharmaceutical versus an appropriate comparator as basis for price negotiations. This is challenging when head-to-head studies (H2H) or randomized placebo-controlled trials (RPTs) are missing and particularly in dermatology, where topical therapies in registration trials are usually compared to their individual vehicle. The aim of this research was to describe different approaches to assess the additional benefit of new topical therapies. **Methods:** To assess 1) how network meta-analyses (NMAs) included within manufacturer submissions to the National Institute for Health and Care Excellence (NICE) have been criticised by its Evidence Review Groups (ERG); 2) how the use of different frameworks might influence the selection of relevant studies; and 3) the extent to which avoidance might increase the likelihood of a new intervention being approved. **Methods:** We reviewed the ERG reports of all NICE technology appraisals published since January 2007 to identify those where the manufacturer’s submission included an NMA. Subsequently all criticisms made by the ERG of such analyses were analysed to seek common themes; and assess how often any one type of criticism was associated with a rejection by NICE. **Results:** A total of 181 NICE technology appraisal reports were evaluated. These covered 243 separate interventional options, 83 (34%) of which were drugs for cancer. Overall 37–64% of submissions cited NMAs, of which 43–83% were criticised, with this proportion having increased over time. Avoidable criticisms related to flaws in the systematic review methodology used to identify relevant RCTs for the analysis, inappropriate pooling of data from heterogeneous studies, and use of suboptimal statistical approaches in conducting the NMA. Unavoidable criticisms related to the lack of RCTs available for competitor drugs in the target population. Therefore, no association was found between flaws in the NMA and a decision by NICE not to approve the use of the intervention. Instead, such rejection was associated mainly with a lack of evidence of clinical effectiveness or a target population of patients. **Conclusions:** Most criticisms of NMAs could be avoided by a more rigorous and transparent approach to conducting and reporting the underlying systematic review and statistical analysis. However, rejection of submissions remains a considerable risk where the underlying evidence is weak.

**PMR190**

**USE OF MULTIVARIATE BAYESIAN EVIDENCE SYNTHESIS TO REDUCE UNCERTAINTY AROUND CLINICAL EFFECTIVENESS AND QUALITY OF LIFE ESTIMATES**

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**OBJECTIVES:** In health technology assessment, decisions about reimbursement of new health technologies are largely based on effectiveness estimates. These estimates are usually also used to predict the health-related quality of life (HRQoL) outcomes, such as EQ-5D, as part of economic evaluation. However, sometimes these effectiveness estimates are not readily available. When many alternative instruments measuring these outcomes are being used (and are not all reported) as part of a network of RCTs, the collection of the common endpoints (and drug development is at an early stage), data on relevant outcomes may be limited. The aim of this study was to develop methodology that would allow synthesis of all available evidence across interventions early and reduce uncertainty around relevant outcomes. **Methods:** Bayesian multivariate meta-analysis