cupola families available and conditional version of the Sklar’s theorem provides theoretical back-ground of using copulatives for copula parameters. The models were fitted by optimizing the pseudo maximum likelihood numerically using the R statistical software. RESULTS: The associations between several biomarker couples were measured by correlation. Pearson’s (r) and Kendall’s (τ) correlations were r = 0.55 and τ = 0.4 for VAS-HAQ and r = 0.66 and τ = 0.48 for VAS-DAS28. Additionally, the bivariate/trivariate dependences were modelled with or without assuming further covariates as e.g. age at first RA diagnosis or the type of therapy etc. The association among subgroups of the RA patients was low. However, the association within different subgroups of the RA patients can be significantly different too. These differences should be taken into account in any further statistical analysis as not only the marginal distributions of biomarkers but their dependence structure can be instrumental in modelling too.

PM133 OPERATIONAL VALIDATION OF HEALTH ECONOMIC DECISION ANALYTIC MODELS
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OBJECTIVES: To validate health economic (HE) models by means of statistical comparison of model outcomes against empirical observations. Such a comparison is structured and the applicability of several existing validation techniques in decision analytic models is limited. Thus, the focus is on statistical testing. When standardised 95%-confidence intervals are used several problems, both of a technical and philosophical nature, are encountered. These problems are discussed. A new statistical application is proposed. METHOD: The proposed method can be applied to validate HE models when the uncertainty around the input parameters of the model is assessed via probabilistic sensitivity analysis (PSA). It is based on the idea of establishing a level of accuracy in advance for the empirical observations and model outcomes. The model result is considered valid if the model result falls within the limits determined by the pre-required accuracy, then the result model is considered valid. The number of valid results obtained in a PSA defines a measure of the reliability of the model. Empirical validation of the method in a framework allows defining such a reliability measure with statistical properties. RESULTS: Existing approaches suffer from technical and interpretational problems. In addition, these methods are lacking a measure of overall reliability. Our new method (1) departs from classical statistical techniques, circumventing the noted problems, (2) can be used for both cohort and patient-level models and (3) makes use of all PSA outcomes. The method is demonstrated with the help of a case study in a published diabetes mellitus (DM) model. RMCA. A Standard framework has to be applied very carefully on the comparison of model outcomes to empirical observations. They suffer from several problems. A new promising Bayesian approach is proposed that solves some of these issues. Our new method allows surrogative validation of the model as new data becomes available, which may increase the model’s validation status.

PM134 A SYSTEMATIC REVIEW AND TAXONOMY OF ECOnOMIC EVALUATIONS OF PHARMACEUTICALS LICENSED ON THE BASIS OF UNCONTROLLED CLINICAL STUDIES
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OBJECTIVES: Pharmaceuticals are usually granted marketing authorisation on the basis of uncontrolled trials (RCTs). Occasionally the efficacy of a treatment is assessed within a randomised comparator group (either active or placebo). Our objective was to identify and develop a taxonomy of economic accounts for pharmaceuticals licensed without randomised control data. METHODS: We searched PubMed, ISPOR Scientific Presentations and the website of the UK health technology assessment (HTA) bodies for assessments of the 75 indications granted a marketing authorisation by the FDA or EMA from Jan-1999 to May-2014 without RCT data. The outcome of interest was the approach to modelling efficacy data. RESULTS: Fifty-one unique models were identified based on 29 peer-reviewed articles, 15 ISPOR abstracts, and 30 health technology appraisals (HTAs). The majority of models (43/51) were based on ‘historical controls’ – comparisons to previous meta-analysis or pooling of trials (5), individual trials (19), registries/case series (14), or expert opinion (7). The majority of drugs granted a marketing authorisation without a RCT had not been evaluated in a published economic model (45/51), with a low rate of submission to UK HTA agencies (28/98). CONCLUSIONS: There is considerable variation in the quality of models constructed for drugs granted a marketing authorisation without a RCT. The most common approach is a naïve comparisons to historical data (using other trials/registry data as a control group), with considerable scope for bias.

PM135 METHODS FOR DETERMINING PATIENT PATHWAY AND RESOURCE USE IN COMPLEX ABDOMINAL WALL RECONSTRUCTION
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OBJECTIVES: Complex abdominal wall reconstruction has been a challenging issue for surgeons for many years, with many factors affecting surgical decision-making and patient outcomes. In particular, complex procedures for ventral hernia repair represent a huge healthcare burden, particularly if two-step rather than one-step reconstruction is used. Effective abdominal wall reconstruction is among the goals of patient management. At present, there appears to be no consistent pathway for the optimal management of these patients, nor is there reliable information on the cost effectiveness of the different. METHODS: META-analysis of the databases that determined the optimal pathway for one- or two-step abdominal wall reconstructions was developed using available literature and surgical input, and was evaluated using a pilot paper-based questionnaire, which was sent to European surgeons with relevant experience. Based on responses, a revised version of the questionnaire was created in an anonymised iPad format for use at surgical conferences. Both the questionnaire and iPad survey aimed to elicit surgical decision-making data regarding types of repair materials used, such as synthetic or biological meshes and the characteristics of these that determine surgical choices. Important additional factors, including co-morbidities, safety, contamination, and risk of recurrence, were included in the questionnaire, as well as the likely length of hospital stay. Use of the Ventral Hernia Working Group guidelines was also questioned in the second stage of this process will collect retrospective resource use data from patient records to determine patterns of care and cost that could improve surgical decision-making and patient outcomes. RESULTS: To date, 16 paper-based questionnaires have been completed (7 in UK (7), Belgium (3), Germany (3) the Netherlands (2) and Italy (1) completed the paper-based questionnaire. CONCLUSIONS: There is sufficient agreement amongst surgeons to produce a patient management pathway, and additional results from ongoing data collection will improve confidence in the consensus.

PM136 HISTOLOGIC BURDEN OF CHRONIC SPONTANEOUS URTICARIA IN COMPARISON TO PSORIASIS: EUROPEAN PERSPECTIVE
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OBJECTIVES: Chronic urticaria (CU) (or chronic hives) can be inducible or spontaneous (also known as idiopathic urticaria) (CSU/CU). Data supporting the impact of CU (or CSU) with other dermatological conditions and PsO are sparse. This study evaluated histamnopic burden associated with CU relative to psoriasis (PsO) and different severity of PsO among the adults in 5 European countries (France, Germany, Italy, Spain and UK) countries. METHODS: Data come from diagnosed CU (DLBEC, IUGR) and PsO patients included in the National Health and Wellness Survey (NHWS). Histamnopic burden was measured through the mental and physical component score (MCS, PCS) of the SF-36v2 and SF-6h health utility score. Self-reported anxiety, depression and sleep difficulty were also assessed. NHWS collects data on PSO severity but not on CU severity. Multiple linear or logistic regression model was used to compare outcomes between patients with CU vs. overall PsO (included all severity levels) and CU vs. moderate-severe PsO, controlling for patient characteristics included in the NHWS (age, sex, region, body mass index (BMI), A697 PsO patients (26.9% moderate-severe) CU patients had lower (worse) MCS (means±SE, 24.2±0.39 vs. 44.6±0.16), PCS (45.2±0.34 vs. 46.8±0.14) and SF-6D score 0.65±0.005 vs. 0.68±0.002) than overall PsO (all p<0.001). Scores for moderate-severe PsO were 43.2±0.25 (p<0.05), 45.7±0.22 (p<NS) and 0.667±0.003 (p<0.05) respectively. CU patients had higher adjusted odds of anxiety, depression and sleep difficulties than overall PsO [odds ratio (OR): 1.63, 1.34 and 1.56, respectively, all p<0.01]. There was no significant difference between moderate-severe PsO (OR: 1.45, 1.12, and 1.36 respectively) and CU patients for the same parameters. CONCLUSIONS: CU and PsO have a negative impact on patients’ quality of life. CU patients report signifi- cantly higher and higher psychological and physical complaints than overall PsO patients. When compared to moderate-severe PsO, patients with CU still have a significantly higher impairment in mental status and lower utility and similar physical impairment and psychological complaints.

PM137 SCORING AND RESPONSIVENESS OF THE SELF-ASSESSMENT OF TREATMENT QUESTIONNAIRE IN PATIENTS WITH PAINFUL DIABETIC PERIPHERAL NEUROPATHY
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OBJECTIVES: The Self-Assessment of Treatment Version II (SAT-II) instrument has three versions: baseline; follow-up (FU); and last-visit versions. Baseline version measures pain level (one item) and impact of pain (six items). Follow-up and last-visit versions measure improvement in the impact or level of pain due to treatment. Last-visit also includes two items about treatment preferences. This study explored scoring of the SAT-II (baseline and last-visit). Scores were also assessed for their responsiveness to change. METHODS: Data from 369 patients (42% female; mean age=63) with painful diabetic peripheral neuropathy from a randomised, double-blind placebo-controlled trial (STEP) were used to test baseline and last-visit versions. Item-to-item spearman correlations and spearman correlations between summary scores and Brief Pain Inventory-Diabetic Neuropathy pain severity score (PSS) were tested. Factor analysis was conducted on the six impact items to develop a score within (baseline) and the sixth item to develop a score within (last-visit). The six impact items was demonstrated for baseline and last-visit. Item-to-item correlations (baseline: correlation (r) = 0.33 to 0.75; last-visit: r = 0.52 to 0.89) and correlations between a sum of the impact items and PSS were significant for baseline (r = 0.51, p<0.001) and last-visit (r = 0.46, p<0.0001). A mean summary score of the impact items discriminated (all p<0.0001) between non-responders and responders, respectively for each definition as follows: > 30%: 0.6 (SD 0.9) vs 1.9 (1.3); >50%, 0.8 (1.1) vs 2.3 (3.3), and PGIC 0.6 (0.7) vs 2.3 (1.3). CONCLUSIONS: The six impact items of the SAT-II can be scored as a summary measure on both the baseline and