observational study. It was conducted from September 2011 to December 2012 and included 1,109 patients who were evaluated in 44 spinal centers (both orthopaedic surgery and neurosurgeries). Patients were diagnosed of having NP if the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale criteria were ≥ 12 points. The patients were investigated to assess their pain using a 0-10 numeric rating scale (NRS) for the worst, average, and minimum level of pain, and their QoL was assessed using the EuroQol (EQ) 5D at baseline, after 1 week and 3 months of the surgery.

**RESULTS:** Among 1,109 patients, at baseline, NP was identified in 404 (36%) patients. At 3 months after surgery, NP was identified in 8.6% and 4.0% patients respectively. Among the 705 patients without NP preoperatively, the prevalence of de novo NP occurred in the 1 week and 3 months of post-surgery was 3.1% and 2.3% respectively. At baseline, NP patients showed lower Qol compared with non-NP patients [0.49 vs 0.53 p<.001]. However, NP patients improved more their QoL compared to non-NP patients after 3 months (0.86 vs 0.84 p = 0.09). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved more than 1 point on the EMA compared to baseline (p=0.11). The pain was relieved by type (i.e., orhan medicines). Products refused and withdrawn were excluded. The PROLabels database was searched for each product retrieved to identify any NP claim in the label. Summary of Product characteristics (SmPC) and CHMP Assessment Reports were retrieved for each product and analyzed to find out about PRO evaluation reported in the AR and not reported in the label. **RESULTS:** Thirteen orphan medicines indicated in lymphoproliferative disorders were identified, representing three main indications: lymphomas (Hodgkin, systemic anaplastic large cell, T-cell lymphoblastic, mantle-cell), leukemias (chronic lymphocytic, hairy cell, acute lymphoblastic) and multiple myeloma. Only one product had a PRO claim: ofatumumab (resolution of constitutional symptoms). The label of another product (brentuximab vedotin) indicated the “resolution of symptoms”. However, there was no mention in the AR on how the symptoms were collected (patient or clinician). For one product (palomide), a HQ evaluation was mentioned in the AR, but not reported in the label. However, there was no information about this evaluation in the AR and the reader is left to wonder about the HQ results and the reasons for not including them in the label. **CONCLUSIONS:** The percentage of PRO claims in orphan medicines (7.7%) is inferior to the percentage of PRO claims in all EMA products (26%). This is remarkably low considering the profound effect of lymphoproliferative disorders on patients’ life. Efforts should be made to improve the reporting of PRO data in the CHMP Assessment Reports.

**PSY83**

**PSYCHOMETRIC VALIDATION OF THE NEWLY DEVELOPED PHENYLKETONURIA- QUALITY OF LIFE (PKU-QOL) QUESTIONNAIRES ASSESSING THE IMPACT OF PHENYLKETONURIA AND ITS TREATMENT ON PATIENTS’ QUALITY OF LIFE**

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**OBJECTIVES:** Phenylketonuria (PKU) is a rare genetic disorder impacting phenylalanine (Phe) metabolism. Treatment involves a lifelong restricted diet that is strict and socially demanding. Even when treated early and well, mild cognitive and growth effects persist, and PKU patients often experience stigmatization from individuals and their families. The phenylketonuria-quality of life (PKU-QOL) questionnaires are the first PKU-specific QOL questionnaires ever developed. The study aimed to perform psychometric validation of these questionnaires and identify a need for refinement of the response scale. The measurement properties of the revised PKU-S will be evaluated in additional web-based and clinic-based quantitatively.

**RESULTS:** The patient-reported outcome (PRO) instrument being developed to assess key impacts, e.g. walking, sitting, standing, etc. associated with chronic low back pain (cLBP). Following a mixed methods approach, the PAL-I development included qualitative tools for focused evaluation of PKU impact on individuals and parents in different experiences: PKU symptoms, impact of PKU, dietary protein restriction and supplementation. Questionnaires were assessed for reliability (internal consistency, test–retest), validity, and content validity. The dataset (306 individuals, ages 9–45 years; 253 parents, ages 24–66 years) were included in the analysis. Return rate and quality of completion of the questionnaires were good, indicating good acceptability. Scores were defined to assess all relevant aspects of experiences: FKU symptoms, impact of FKU, dietary protein restriction and supplementation. Reliability and validity were satisfactory overall for the adolescent, adult and parent FKU-QOL questionnaires, and slightly weaker but acceptable for the child version. **CONCLUSIONS:** The four PKU-QOL questionnaires are valid and reliable instruments for assessing the specific quality of life aspects that are affected in individuals with FKU of different age groups (children, adolescents and adults) and their parents, and are available in seven languages. They are very promising tools for focused evaluation of FKU impact on individuals and parents in different countries, and for monitoring the efficacy of therapeutic strategies.

**PSY84**

**PRO CLAIMS IN ORPHAN MEDICINES APPROVED BY THE EUROPEAN MEDICINES AGENCY (EMA) FOR THE TREATMENT OF LYMPHOPROLIFERATIVE DISORDERS**

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**OBJECTIVES:** 1) To identify orphan medicines indicated for lymphoproliferative disorders approved by the European Medicines Agency (EMA); 2) To identify medicines for which a PRO evaluation was performed; (3) To list those with a PRO labeling claim, and (4) To identify reasons for not granting a PRO claim. **METHODS:** The search was conducted on 07/21/2014. **RESULTS:** Sixteen orphan medicines were identified by type (e. g. orphan medicines). Products refused and withdrawn were excluded. The PROLabels database was searched for each product retrieved to identify any PRO claim in the label.Summary of Product characteristics (SmPCs) and CHMP Assessment Reports were retrieved for each product and analyzed to find out about PRO evaluation reported in the AR and not reported in the label. **RESULTS:** Thirteen orphan medicines indicated in lymphoproliferative disorders were identified, representing three main indications: lymphomas (Hodgkin, systemic anaplastic large cell, T-cell lymphoblastic, mantle-cell), leukemias (chronic lymphocytic, hairy cell, acute lymphoblastic) and multiple myeloma. Only one product had a PRO claim: ofatumumab (resolution of constitutional symptoms). The label of another product (brentuximab vedotin) indicated the “resolution of symptoms”. However, there was no mention in the AR on how the symptoms were collected (patient or clinician). For one product (palomide), a HQ evaluation was mentioned in the AR, but not reported in the label. However, there was no information about this evaluation in the AR and the reader is left to wonder about the HQ results and the reasons for not including them in the label. **CONCLUSIONS:** The percentage of PRO claims in orphan medicines (7.7%) is inferior to the percentage of PRO claims in all EMA products (26%). This is remarkably low considering the profound effect of lymphoproliferative disorders on patients’ life. Efforts should be made to improve the reporting of PRO data in the CHMP Assessment Reports.

**PSY85**

**EVALUATING RELATIONSHIP BETWEEN WHITE BLOOD CELLS AND PLATELETS DURING RECOVERY PHASE IN DENGE HEMORRHAGIC FEVER CASES IN PUNJAB, PAKISTAN: A RETROSPECTIVE STUDY**

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**OBJECTIVES:** Denge infection is a major cause of disease in tropical areas with an estimated 50 million infections occurring each year and more than 2.5 billion people being at risk of infections. The main objective of this study was to investigate relationship between white blood cells and platelets during dengue hemorrhagic fever. **METHODS:** A retrospective multi-center study was conducted on 1000 seropositive cases of dengue fever. **RESULTS:** More prevalence has been observed in male (580 (88%)) as compared to female (320 (12%). A rapid fall in white blood cell counts (WBC) was observed in initial CBC reports at start of disease then...