Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30), a PRO instrument specifically designed to measure HRQoL of cancer patients. HRQoL was measured at screening, months 1, 3, 7, and at re-puncture. Meaningful deterioration was defined as a decrease in HRQoL scores of at least 5 points. Time to first meaningful deterioration was compared between catumaxomab (N=160) and control (N=85) groups using survival analysis techniques such as log-rank test and Cox models. **RESULTS:** Deterioration in HRQoL scores appeared more rapidly in the control group than the catumaxomab group (medians: 16-28 days vs. 45-49 days). The difference between the two groups in time to deterioration in HRQoL was statistically significant for all scores ($p<0.01$). Results were confirmed with Cox models ($p<0.05$). Hazard ratios ranged from 0.08 to 0.24. **CONCLUSIONS:** Treatment with catumaxomab delayed deterioration in HRQoL in patients with MA compared to paracentesis alone. The findings of this study indicate that the gain of puncture free survival due to catumaxomab treatment previously reported (Heiss et al. 2010) translates into a HRQoL benefit for the patients.

PCN118

IMPACT OF BONE METASTASES ON QUALITY OF LIFE IN PATIENTS WITH CASTRATION-RESISTANT PROSTATE CANCER (CRPC) AT HIGH RISK FOR DEVELOPING BONE METASTASES

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OBJECTIVES: The majority of patients with prostate cancer progress to CRPC and frequently develop bone metastases. Treatment and management of bone metastases, as well as the underlying disease, influences the patient's quality of life. We evaluated the impact of bone metastases on utility (using EQ-5D) and quality of life (using FACT-P) in high-risk CRPC patients. **METHODS:** Data were extracted from the Adelphi Real World Prostate Cancer Disease-Specific Programme© (DSP), a cross-sectional survey of 348 urologists and oncologists and their prostate cancer patients that was conducted between December 2009 and May 2010 in France, Germany, Italy, Spain and the UK. Physicians completed comprehensive record forms on 10 patients being actively treated for prostate cancer. Patients could also complete a questionnaire, which included the EQ-5D and FACT-P tools, however this was not compulsory. **RESULTS:** Of the 3,477 prostate cancer patients for which data were collected, 1,180 (34%) were categorised as having CRPC with a median time since diagnosis of 35.8 months. 146 patients with CRPC were identified as being at high risk for developing bone metastases (Gleason score ≥8, or a most recent PSA of ≥8ng/mL, or a PSA DT ≤10 months, or had received local therapy in addition to systemic medication). High-risk CRPC patients had an average EQ-5D index of 0.77 (n=36) and FACT-P of 99.54 (n=27). In contrast, patients with CRPC and bone metastases (n=680) had an average EQ-5D index of 0.59 (n=165) and FACT-P of 82.99 (n=147). Statistical differences were observed between the high-risk and bone metastases groups for both EQ-5D ($p=0.0002$) and FACT-P ($p=0.0007$). **CONCLUSIONS:** The development of bone metastases represents a significant additional burden for patients with CRPC highlighting the need for new treatments capable of preventing bone metastases in these patients.

PCN119

PATIENT-REPORTED OUTCOMES (PROS) IN ANTINEOPLASTIC PRODUCT APPROVALS IN EUROPE AND IN THE USA

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OBJECTIVES: (1) To identify antineoplastic agents approved with a PRO labeling claim in Europe and the USA; (2) To review the types of PROs used for these approvals; and (3) To list the differences found between Europe and the USA in terms of products and labeling. **METHODS:** The search was performed on the FDA and EMA approved medicinal product labels (from 1995 to 2010). The review was conducted through a systematic manual review of antineoplastic product labelings. All documents were read individually by two independent raters. **RESULTS:** A total of 138 antineoplastic products were retrieved: 55 approved by the EMA, 83 by the FDA. Nineteen products with a PRO claim were identified: eight the USA, 11 in Europe. Most of the PROs identified in the claims were symptoms or function. HRQL was mentioned for 11 products: nine in Europe, two in the USA. PROs were primary endpoints in two cases (advanced cancers). Nine products approved by both agencies showed discrepancies in terms of PRO labeling: the EMA gave a PRO claim to eight products, but not the FDA; and the FDA gave a PRO claim to one product, but not the EMA. In most cases, the reviews of both agencies were conducted on the same material. The comparison of the products with a PRO labeling claim approved by the EMA but refused by the FDA showed that the FDA questioned the quality of the study design, the analyses, or the questionnaires' content validity. **CONCLUSIONS:** Our review showed that the patients' perspective in clinical oncologic research is important for the EMA and FDA. However, the patients' perspective is not considered sufficient on its own: PROs are rarely used as primary endpoints except for assessing palliative response. Our analysis suggests that there is high receptivity of EMA to HRQL as a concept.

PCN120

QUALITY OF LIFE AMONG GERMAN PATIENTS WITH METASTATIC CASTRATION-RESISTANT PROSTATE CANCER

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Treatment of metastatic castration-resistant prostate cancer (mCRPC) is primarily palliative and patients' quality of life (QoL) is considered an important treatment goal. Nevertheless, little is known about QoL of mCRPC patients. **OBJECTIVES:** To assess QoL outcomes in mCRPC patients in Germany. **METHODS:** 1-year observational, cross-sectional, prospective study conducted in Germany by 37 prostate-cancer (PC) specialised centres. The study included patients with confirmed PC diagnosis and metastatic castration-resistant disease. EQ-5D and FACT-P questionnaires were completed by patients at inclusion visit. Patient characteristics were collected by physicians. Interim results based on 101 of 281 patients in total, are presented. **RESULTS:** Mean age was 73.2 years. At inclusion, 32.6% had never been treated with chemotherapy (no CT), 36.8% had been treated with chemotherapy previously (past CT) and 30.5% were currently undergoing chemotherapy (ongoing CT). Mean time since PC diagnosis was 7.2 years (respectively 8.7, 6.6 and 4.0 years for no CT, past CT and ongoing CT). 34.0% of patients had metastases at diagnosis. Mean (SD) EQ-5D single index utility score was 0.72 (0.30) (respectively 0.81 (0.27), 0.66 (0.30), 0.64 (0.31) for no CT, past CT and ongoing CT). 67.3% of patients exhibited pain or discomfort, 58.1% problems to perform usual activities, 53.1% mobility problems, 37.7% anxiety/depression troubles and 32.7% self-care problems. Mean (SD) EQ-5D VAS score was 47.8 (23.6). Mean (SD) FACT-P total score was 101.5 (25.2) (respectively 106.0 (27.1), 95.2 (21.6) and 103.5 (26.7) for no CT, past CT and ongoing CT). Mean (SD) subscale scores were: physical well-being: 19.5 (6.6), social/family well-being: 20.6 (5.6), emotional well-being: 17.0 (4.8), functional well-being: 15.7 (6.3) and PC subscale: 28.6 (9.0). **CONCLUSIONS:** The interim analysis provides first trends on QoL in German mCRPC patients. Final analyses are expected to clarify determinants of QoL and in particular the impact of chemotherapy.

PCN121

DECITABINE REDUCES TRANSFUSION DEPENDENCE IN OLDER PATIENTS WITH ACUTE MYELOID LEUKAEMIA: RESULTS FROM A POST-HOC ANALYSIS OF A RANDOMISED PHASE III TRIAL

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OBJECTIVES: The incidence of acute myeloid leukaemia (AML) increases with age; older patients have limited treatment options and poorer outcomes. Dependence on blood transfusions (correcting anaemia and preventing bleeding) and repeated hospitalisation reduce health-related quality of life and increase treatment expenditure. This post-hoc analysis assessed the impact of decitabine on transfusion dependence. **METHODS:** The DACO-16 phase III trial (NCT00260832) was conducted in newly-diagnosed AML patients (≥65 years; N=485) (*Kantarjian, JCO*; ePub 11Jun2012). Every 4 weeks, patients received decitabine (DACOGEN) 20 mg/m2 (1-h intravenously; 5 successive days) or treatment choice with physician's advice (TC) with supportive care or cytarabine (20 mg/m^2 subcutaneously daily; 10 successive days). Treatment duration was longer in the DACOGEN than TC arm (median: 4 cycles vs. 2 cycles). We measured red blood cell (RBC) and platelet (PLT) transfusion-independence (no transfusions for ≥ 8 consecutive weeks) and hospitalisation length (% hospital nights relative to treatment days) in both DACOGEN (n=242) and TC (n=243) arms. **RESULTS:** In patients who were PLT transfusion-dependent at baseline (85 in DACOGEN and 83 in TC arms), more became transfusion-independent in the DACOGEN arm (26 [31%]) than the TC arm (11 [13%]) ($p=0.0069$). Likewise, in RBC transfusion-dependent patients at baseline (168 in DACOGEN and 162 in TC arms), transfusion-independence was higher for DACOGEN (44 [26%]) than TC (21 [13%]) ($p=0.0026$). For hospitalised patients (182 in TC, 191 in DACOGEN arms), the median % of hospital nights was higher in the TC arm (39%) than the DACOGEN arm (34%). Similarly, for adverse event-hospitalised patients (100 in TC, 132 in DACOGEN arms), the median was 20.0% vs. 17.5% in the TC and DACOGEN arms, respectively. **CONCLUSIONS:** Dacogen leads to a statistically-significant reduction in transfusion-dependence, when compared with TC. This reduction is an important factor in the economic and humanistic burden of AML in older patients.

PCN122

PILOT SURVEY TO ESTIMATE WILLINGNESS TO PAY (WTP) FOR PROPHYLACTIC GRANULOCYTE COLONY-STIMULATING FACTORS (G-CSFS) AMONG PREVIOUSLY TREATED BREAST CANCER PATIENTS

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OBJECTIVES: G-CSFs can decrease the incidence of febrile neutropenia (FN) among cancer patients receiving highly myelosuppressive chemotherapy regimens. The primary objective of this pilot study was to determine the feasibility of a discrete choice survey on prophylactic G-CSF (pegfilgrastim and filgrastim) use in patients diagnosed with breast cancer as well as refine the survey instrument before proceeding with the full study population. **METHODS:** A web-based discrete choice survey of patients diagnosed with breast cancer, and previously treated with chemotherapy, was conducted. The pilot survey was developed based on literature review, clinical consultation and 6 in-depth and 4 pre-test interviews with breast cancer patients. The experimental design was generated using Sawtooth software with 16 paired treatment-scenarios, comparing pegfilgrastim to filgrastim at 6- or 11-doses with a follow-up "no treatment" option. The 5 attributes included: frequency of treatment, inconvenience of treatment, risk of disruption to chemotherapy schedule due to low white blood cell counts, risk of developing an infection requiring hospitalization, and patient out-of-pocket cost. Demographics, clinical characteristics, health care costs and attitudinal data were also collected.