trials. One such measure is the FACT-Leukemia questionnaire (FACT-Leu), which evaluates the quality of life (QOL) of leukemia patients. **METHODS:** This study set out to linguistically validate the FACT-Leu for use in Argentina, Austria, Belgium, Bulgaria, Canada, Chile, China, Croatia, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, India, Israel, Italy, Japan, Korea, Latvia, Lithuania, Malaysia, Mexico, The Netherlands, Norway, Poland, Romania, Russia, Serbia, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Taiwan, Thailand, Turkey, Ukraine and Venezuela. The study sample consisted of 758 patients (444 males/310 females/4 missing) diagnosed with leukemia. Patient mean age was 47 years, and at the time of administration, 628 patients were receiving medical treatment. The sample consisted of patients who speak 43 languages collectively. The FACT-Leu was translated according to the standard FACIT methodology. Patients diagnosed with Leukemia completed the respective translated questionnaire and then participated in a cognitive interview to determine if there were any problems with the translations or item content. Quantitative analyses (descriptive statistics and reliability analyses) were performed on the combined sample and participant comments were analyzed qualitatively in order to confirm the validity of the translations. **RESULTS:** The FACT-Leu translations exhibited good internal reliability and linguistic validity. The alpha coefficient for the questionnaire as a whole including all languages was 0.96. Subscale alphas ranged from 0.81 to 0.91, also indicating good internal consistency. All items on the FACT-Leu correlated at an acceptable level. **CONCLUSIONS:** The FACT-Leu demonstrated acceptable reliability and linguistic validity in all 43 languages. We consider these translations acceptable for PRO assessment in international research and clinical trials.

PCN136

COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM) USE AMONG LOCAL STAGE PROSTATE CANCER PATIENTS: TYPES, FACTORS ASSOCIATED WITH USE AND PERCEIVED BENEFITS

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OBJECTIVES: Little is known about CAM use among prostate cancer patients. This study describes CAM use, patient factors that predicted CAM use, and satisfaction with CAM among men with local stage prostate cancer. **METHODS:** Newly diagnosed local stage prostate cancer patients in California and Washington State completed self-administered surveys. Patients were asked about sources of information they used to learn about prostate cancer, and at six months, about types of CAM they were using and satisfaction with those therapies. **RESULTS:** A total of 512 men completed baseline surveys before treatment and six-month follow-up surveys. 261 (51%) reported using CAM at follow-up. The average age was 65; 69% were white, 11% black, 10% Asian; 128 (49%) had "low risk" local stage prostate cancer by PSA and Gleason score. The most common forms of CAM utilized included personal prayer (n = 148, 57%), herbs or dietary supplements (n = 86, 33%), and special diets (n = 84, 32%). Fifty-one percent used one type of CAM, 26% used two, and 22% used three or more. In multivariate analysis, patients were significantly more likely to use CAM if they had consulted medical literature (OR 1.96, CI 1.23–3.11) or talked with friends or family members (OR 1.76, CI 1.17–2.64). Prostate cancer risk group, comorbidities, age, race, education level, marital status, employment, and income were not significantly associated with CAM use. Most described CAM as "very" or "somewhat" helpful" (92%). Many CAM users [43% (n = 113)] did not discuss CAM with a health professional. **CONCLUSIONS:** In this multi-site study, more than half of all men with local stage prostate cancer reported using CAM. Race and education were not predictors of use. A substantial minority of CAM users did not discuss these treatments with their physician. Since no CAM approach has demonstrated benefit for local stage prostate cancer, future research should examine men's perceptions of the benefits.

PCN137

ONCOLOGY PATIENT-REPORTED CLAIMS: MAXIMISING THE CHANCE FOR SUCCESS

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OBJECTIVES: To review PRO labelling claims achieved in oncology in Europe and in the US and consider the benefits, and challenges faced. **METHODS:** PROLabels database was searched to identify oncology products with PRO labeling approved in Europe since 1995 or in the US since 1998. FDA and EMEA websites and guidance documents were reviewed. PUBMED was searched for articles on PRO claims in oncology. **RESULTS:** Among all oncology products approved, 19 were identified with PRO claims; nine in the U.S, five in Europe, and five in both. The language used in the labelling was limited to benefit (e.g. "…resulted in symptom benefits by significantly prolonging time to deterioration in cough, dyspnoea, and pain, versus placebo") and equivalence (e.g. "no statistical differences were observed between treatment groups for global QOL"). Seven products used a validated HRQL tool; two used symptom tools; two used both; seven used single-item symptom measures (one was unknown). The following emerged as likely reasons for success: ensuring systematic PRO data collection; clear rationale for pre-specified endpoints; adequately powered trials to detect differences and clinically significant changes; adjusting for multiplicity; developing an a priori statistical analysis plan including primary and subgroup analyses, dealing with missing data, pooling multiple-site data; establishing clinical versus statistical significance; interpreting failure to detect change. End-stage patient drop-out rates and cessation of trials due to exceptional therapeutic benefit pose significant challenges to demonstrating treatment PRO improvement. **CONCLUSIONS:** PRO labelling claims demonstrate treatment impact and the trade-off between efficacy and side effects ultimately facilitating product differentiation. Reliable and valid instruments specific to the desired language, claim, and target population are required. Practical considerations include rationale for study endpoints, transparency in assumptions, and attention to subtle variations in data.

PCN138

INFORMATION NEEDS: A STUDY ABOUT ONCOLOGICAL PATIENTS IN THE ITALIAN CONTEXT

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OBJECTIVES: The identification and management of unmet supportive care needs is an essential component of health care for people with cancer. The study aimed to evaluate the informative, psychological, social, and practical needs, focusing on information needs over two consecutive (one-month) assessments. **METHODS:** The study was a longitudinal research. A total of 245 consecutive patients at IDI-IRCCS, Rome, were enrolled. They filled the Edmonton Symptom Assessment System (ESAS) and the Need Evaluation Questionnaire (NEQ) at baseline and one month later (n.115). The psychometric properties of questionnaires have been well documented in literature. ESAS is a questionnaire with 10 items describing cancer related symptoms in the visual analogue scales. NEQ is a standardized questionnaire for psychosocial needs. Multiple logistic regressions were used to examine the association between information needs and patient characteristics. **RESULTS:** Patients need more information about their own disease condition (preference information ranking: prognosis, treatment, exams, diagnosis). Patients with higher education (OR 2.20; $p = 0.052$) need to be more informed about diagnosis and more involved in their therapeutic choices (OR 2.37; $p = 0.053$). Women need physicians to be more sincere with them (OR 2.70; $p = 0.029$). Patients, positive to the question on ESAS depression (cut off ≥7) believe they need more explanations about treatments ($p = 0.005$), more comprehensible information from health personnel ($p = 0.015$), more sincerity ($p = 0.039$) and more reassurance by clinicians ($p = 0.007$) compared to the negative ones.Still the information needs seem to be stable over time: 70 % of patients showed similar ranking at follow-up. Patients with modified needs at the one-month assessment (30%) are equally divided into two groups. No statically significant differences were observed between groups. **CONCLUSIONS:** The results of the study showed that monitoring patients understanding and preferences for information, in the complex process of patient-physician communication, is relevant to tailor exhaustive explanation for each patient.

PCN139

FINAL QUALITY OF LIFE (QOL) RESULTS WITH GEOGRAPHICAL ANALYSIS FOR SUNITINIB VERSUS INTERFERON-ALFA, AS FIRST-LINE THERAPY IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA (MRCC)

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OBJECTIVES: In a randomized, phase III trial, sunitinib showed superior progression-free survival over interferon-alfa (IFN-α), 11 vs. 5 mo, respectively ($P < 0.001$), as first-line mRCC therapy; median overall survival with sunitinib was >2 years (Motzer, 2009). Here, we report final QOL results from this trial. **METHODS:** 750 treatment-naïve mRCC patients were randomized 1:1 to receive sunitinib 50 mg orally once-daily in 6-week cycles (4 weeks on drug, 2 weeks off), or IFN-α 9 MU subcutaneously thrice-weekly. QOL was measured by 9 endpoints: Functional Assessment of Cancer Therapy–General (FACT-G), which has 4 subscales; FACT-Kidney Symptom Index–15 item (FKSI-15), which includes a Disease-Related Symptoms (FKSI-DRS) subscale (primary QOL endpoint); and EQ-5D questionnaire's utility index (EQ-5D Index) and visual analog scale (EQ-VAS). Higher scores indicated better outcomes. Patients completed questionnaires on days 1 and 28 of each cycle. Data were analyzed for the intent-to-treat population using mixed-effects models (MM), supplemented with pattern-mixture models (PMM). We also compared QOL of patients in the US and EU (France, Germany, Italy, Poland, Spain and UK). **RESULTS:** Patients on sunitinib reported better FKSI-15 and FKSI-DRS scores than those on IFN-α, with a significant difference in overall means across cycles (4.06 and 2.36, respectively; $P < 0.0001$; MM). Similarly, differences in means for FACT-G (and all subscales), EQ-5D Index, and EQ-VAS all significantly favored sunitinib ($P < 0.05$). Per pre-established thresholds, between-treatment differences in mean scores were clinically meaningful for FKSI-15, FKSI-DRS, FACT-G, and the FACT-G functional well-being subscale. In the US, all endpoints, except the EQ-5D index score, significantly favored sunitinib over IFN-α ($P < 0.05$). In the EU, 5 of 9 endpoints significantly favored sunitinib over IFN-α ($P < 0.05$). Across all analyses, PMM and MM results were similar. **CONCLUSIONS:** Sunitinib provides superior QOL over IFN-α, in addition to superior efficacy, as first-line mRCC therapy, with similar findings in the US and EU.