OBJECTIVES: In economic evaluations in oncology, survival data is typically extrapolated without taking into account prognostic factors. If individuals' level trial data are available, patient and disease characteristics observed at baseline are considered. However, survival models typically disregard information that are not known at baseline, e.g. response to treatment, but that may be valuable for the prognosis of patients and hence decision making. In this study we present a survival model that included response to treatment over time.

METHODS: Data from 99 patients with late-stage soft tissue sarcoma from a clinical trial was used. Survival distribution and the percentage change in the sum of the longest diameters of target lesions (i.e. the basis for response evaluation) measured repeatedly during follow-up were utilized. A joint model was estimated linking a random effects sub-model for the change of tumor size with a Weibull sub-model for the survival outcome. The association between changes of tumor size over time and overall survival was assessed. Several different functional forms were explored to model the tumor size data and the best fitting model was selected.

RESULTS: The model was followed in the trial (126 time points in 63 patients over an average age, 4.8 measurements on tumor size were available per patient. A flexible cubic B-spline sub-model provided the repeatedly measured tumor size change data the best model fit. The association between tumor growth and overall survival was mainly statistically significant with a P-value of less than 0.10.

CONCLUSIONS: The presented joint model demonstrated that response to treatment over time may be important to consider when building survival models for health economic evaluations in oncology. The model explicitly incorporated the heterogeneity of patients not observed at baseline providing a clinically relevant survival model. Individual survival predictions can be prepared using patient-specific history of tumor growth.

RESEARCH ON METHODS – Patient-Reported Outcomes Studies

PMR135 ASSESSMENT OF THE HUNTINGTON QUALITY OF LIFE INSTRUMENT (H-QOL-I) CROSS-CULTURAL VALIDITY

1Creative-Ceutical, Paris, France, 2Creative-Ceutical, Les Berges du Lac, Tunisia, 3Neurogenetics and Rare Disease Centre, IRCCS Neuromed, Pozzuoli, Italy, 4Creative-Ceutical USA, Chicago, IL, USA, 5University of Aarhus, Aarhus, Denmark, 6Poznan University of Medical Sciences, Poznan, Poland, 7Hospital Ramón y Cajal, Madrid, Spain, 8University of Marseille, Marseille, France

OBJECTIVES: The Huntington Quality of Life Instrument (H-QOL-I) is the first self-reported, specific instrument developed to assess the health-related QoL (HRQoL) of patients with Huntington's disease (HD). It includes three subscales: motor (4 Likert-type items), psychological (4 Likert-type items) and socializing (3 Likert-type items). The aim of the study was to assess whether patients from different countries and the H-QOL-I, internationally, responded differently to the H-QOL-I.

METHODS: Data were from the European study of HD burden (EURO-HD) survey and included data across 6 countries: France, Germany, Italy, Spain, Poland and the USA. The Differential Item Functioning (DIF) method was adopted to examine whether patients from different countries with the same characteristics had different probability of giving a certain response on H-QOL-I. An item was considered as displaying a DIF if the associated p-value were calculated for each item and for all pairs of countries (i.e. 15 combinations).

RESULTS: The study included 633 patients (176 French, 124 Italian, 44 German, 60 Polish, 59 Spanish and 170 American). Almost all the items (24 of 26) didn’t show any cross-cultural difference. The two items showing DIF were related to the dimension "precise movement" and were detected in the Spanish-US comparison (A56 [left hand] = 0.2165, A57 [right hand] = 0.1618) and in the Spain-France comparison (A52 [left hand] = 0.1571, A51 [right hand] = 0.1578).

CONCLUSIONS: Globally, these data support the H-CSRI cross-cultural validity. Further analyses should be conducted to confirm if those particular items need to be revised in the Spanish version.

PMR137 CROSS-CULTURAL VALIDITY OF THE HUNTINGTON QUALITY OF LIFE INSTRUMENT: CROSS-CULTURAL VALIDITY OF THE HUNTINGTON QUALITY OF LIFE INSTRUMENT; VALIDATION OF THE GERMAN VERSION OF THE OCCUPATIONAL CONTACT DERMATITIS SEVERITY INDEX (ODD)

Aubleicher C1, Postelnicu A2, Rauer A, Diepgen TL, Eißen P, Dawson R, Mahler V, Molin S, Umbach C1, Weissbach T, Hofmann C1, Przybilla B
1University of Regensburg, Regensburg, Germany, 2TransPerfect, Boston, MA, USA.

OBJECTIVES: The ODDi was designed in Australia to measure severity and functional disability in patients with occupational contact dermatitis (OCD). The psychometric properties of the German version of the ODDi are unclear. Our objective was to investigate the validity and reliability of the German ODDi version.

METHODS: The ODDi was translated and linguistically validated into German for Germany, following industry-standard procedures of concept, forward-back translation and reconciliation, and clinician review. The German version was available, data was drawn from the baseline assessment (T1) and first follow-up (T2) in a German chronic hand eczema (CHE) registry. We tested the correlations of the ODDi with reference measures were computed to assess validity. Cronbach’s alpha was calculated as a measure of internal consistency and the intraclass correlation coefficient to assess retest-reliability.

RESULTS: 152 patients (54.5% female, mean age: 45.1 years) were included in the study. Cronbach’s alpha was found to be 0.79. Correlations of the ODDi total and the Dermatology Life Quality Index (rho=0.36) as well as the PGA (rho=0.48) and patient-assessed disease severity (rho=0.40) were of modelled approach to the MCID. The model (1.29) was found to be smaller than the SD (1.87).

CONCLUSIONS: The German ODDi version is reliable and valid to measure functional impairment and disease severity in patients suffering from OCD. The MCID falls within the range of measurement error and should not be used.

PMR138 MAPPING FACT-P TO EQ-SD IN METASTATIC CAstration-RESISTANT PROSTATE CANcer (mCRPC) PERFORMANCE OF A previously DEVELOPED ALGORITHM WHEN APPLIED ON A SAMPLE WITH A DIFFERENT DISEASE STAGE (BENCIVENCI L, Longworth L1, Skaltsa K, Holstrom S4

Cláudio Bencivenici, Holmström S4

OBJECTIVES: To evaluate the predictive performance of a previously published mapping algorithm to EQ-5D utility in prostate cancer patients with metastatic castration-resistant prostate cancer (mCRPC).

METHODS: Data were obtained from a randomized, double-blind, placebo-controlled phase 3 trial in asymptomatic/mildly symptomatic mCRPC patients. The mapping model was developed using mCRPC patients in a post-chemo setting, included the FACT-P subscale scores and baseline variables and used separate algorithms for patients with good and poor health defined as a FACT-P score exceeding or not 76. Model performance was assessed by mean absolute error (MAE) and root mean squared error (RMSE).

RESULTS: The testing dataset contained 1,669 patients with baseline and ≥1 post-baseline scores. The average baseline EQ-5D utility and FACT-P total score were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively. Percentage of people with baseline and post-baseline scores were 0.844 and 119.5 respectively.

CONCLUSIONS: The model predicts well for milder health states, but overpredicts for the more severe ones (EQ-5D utility: 0.5, MAE: 0.436, RMSE: 0.258, EQ-5D utility: 0.5, MAE: 0.496, RMSE: 0.129). Although external validation is recommended using similar samples, our findings show that the algorithm developed in the post-chemo setting performed well in a pre-chemo setting in mCRPC patients, although over-predicts for severe states. This model seems suitable for predicting utility values for economic evaluation when a preference-based measure is absent in chemo-naïve and in the Spain-France comparison (R2 = 0.150)

CONCLUSIONS: The model predicts well for milder health states, but overpredicts for the more severe ones (EQ-5D utility: 0.5, MAE: 0.436, RMSE: 0.258, EQ-5D utility: 0.5, MAE: 0.496, RMSE: 0.129). Although external validation is recommended using similar samples, our findings show that the algorithm developed in the post-chemo setting performed well in a pre-chemo setting in mCRPC patients, although over-predicts for severe states. This model seems suitable for predicting utility values for economic evaluation when a preference-based measure is absent in chemo-naïve and in the Spain-France comparison (R2 = 0.150).