METHODS: Patient relevant endpoints of treatment (remission of depression, response to treatment, no relapse, serious adverse events, adverse events, social function, anxiety, pain, cognitive function) were prioritized with pairwise comparisons of these outcomes. In two separate groups, twelve patients and seven experts judged on a 9 point scale the relative importance of pairs of two outcome measures. The geometric mean of these judgments was used to derive weighting factors for the outcome measures (scale 0–1). RESULTS: Of all outcome measures, patients rated response to treatment highest (0.32), while experts rated remission of depression highest (0.48). Adverse events were all rated lowest by patients as well as by experts, and disease-specific quality of life domains such as social function (0.11 & 0.09), anxiety (0.12 & 0.05) and cognitive function (0.13 & 0.06) were rated in between. CONCLUSIONS: The most important outcome measures according to the patients are, in order of decreasing importance: response, cognitive function, no anxiety, social function, relapse, no adverse events, and remission. The AHP appears to be suitable in gaining an overview of the importance of patient relevant outcome measures. An additional advantage of AHP is that the group discussions offer insight in the question why the endpoints are important.

THE SUBJECTIVE WELL-BEING UNDER NEUROLEPTIC SCALE SHORT FORM (SWN-K20) AND THE SF-36 AS QUALITY OF LIFE MEASURES IN SCHIZOPHRENIC PATIENTS
Sanchez J1, Haro F2, Martin P, Diaz T4, Bullerstros J5
1University of Valencia, CIBERSAM, Valencia, Spain; 2Parc Sanitari Sant Joan de Deu, CIBERSAM, Sant Boi de Llobregat, Spain; 3Astrazeneca, Madrid, Spain; 4Astrazeneca, Zaventem, Brussels, Belgium; 5University of the Basque Country UPV/EHU, CIBERSAM, Leioa, Spain
OBJECTIVES: Outcomes research in patients with schizophrenia should take into account the subjective interpretation of the mood and physical changes accompanying medication. Those changes influence the behavioural response to treatment and ultimately the patient’s clinical outcome as mediated by his treatment compliance. Our aim was to assess the relationship between a specific well-being measure, the SWN-K20 that presents a general and specific measurement subdomains (mental functioning, social integration, emotional regulation, physical functioning, and self-control), and the 8 domains of the SF-36 v1 as a general quality of life measure. METHODS: The validation sample for this study comprised 97 patients diagnosed with schizophrenia and who were rated as clinically stable at the moment of the study (1 week test-retest intraclass correlation coefficient for clinical symptoms = 0.96). The patients were recruited from a multicenter psychometric trial to validate the SWN-K20 in Spanish. The associations between the domains of the SWN-K20 and the SF-36 were evaluated by the Spearman’s rank correlation test. RESULTS: All correlations among domains were positive and most were statistically significant (p < 0.05). As expected the bodily pain domain of the SF-36 presented the lower correlations with the SWN-K20 (rho range of 0.10 to 0.25), whereas the other 7 domains correlated significantly with the total SWN-K20 score (rho range 0.49 to 0.60, all p < 0.001). Overall the largest correlations were obtained between the SWN-K20 and the SF-36 domains of general health (rho = 0.53), mental health (rho = 0.60), and vitality (rho = 0.54). CONCLUSIONS: The positive but nevertheless moderate correlations observed between a specific well-being scale, as the SWN-K20, and a general quality of life scale, as the SF-36, supports the inclusion of specific and diagnose-tailored instruments for outcome assessments of patients with schizophrenia.

INNOVATIONS IN COMBINING PATIENT REPORTED OUTCOMES WITH COGNITIVE TESTING DATA TO STREAMLINE AND LEVERAGE REAL-TIME DATA COLLECTION
Curry C
PfS Corporation, Boston, MA, USA
OBJECTIVES: Understand features of an electronic device that allow a marked improvement in the quality of collected data; the importance of improved data quality leading to enhanced patient safety and drug labeling; populations best suited for paired PRO and cognitive measurement technologies; important practical considerations for implementation in clinical trials including training and compliance; the potential for using real-time parallel data for adverse event safety monitoring. METHODS: This session will review PRO and biomarker technology for parallel data collection, emphasizing advantages, disadvantages, execution, and ways to leverage these data. The session will review PRO and cognitive testing technologies, including comparisons of devices that combine physiological measures with a patient interface with systems that use separate PRO input and biometric devices. RESULTS: Assessing the ability to enhance or prohibit reduction of cognitive processing efficiency is an emerging study in the pharmaceutical industry. Case studies examine how the use of cognitive function tests in combination with ePRO can enhance the data collection so drug effects otherwise unidentified can be determined. The speaker will discuss the future of ePRO combined with biometric measures as a standard of clinical research. CONCLUSIONS: Clinical trial endpoints can involve collection of physiologic and patient-reported outcome data; a combination of subjective and objective data. Electronic forms of information capture assure trial efficiencies including edit checks and shorter time to database lock. ePRO provides time-stamped, legible and complete data from subjects. Biometric devices capture the physiological measurements. Typically, cognitive data have been collected from patients separately from PRO data during clinical trials, increasing respondent burden and risk of error such as transposing manually entering data. The use of ePRO and biometric devices, evolution of data transmission technology, and greater technological sophistication of consumers, provide the opportunity for parallel electronic date capture, simultaneously capturing and transmitting physiologic and PRO parameters in clinical studies.