OBJECTIVES: To evaluate the cost effectiveness of capecitabine + docetaxel combination versus docetaxel alone in the treatment of advanced and/or metastatic breast cancer in France. METHODS: This analysis was based on primary data from an open-label, randomized, multi-centre phase III clinical trial (SO14999). Unit costs reflecting the French economic context was attached to patients’ use of resource, i.e. reference tariffs for consultations, daily treatment costs for drugs and mean cost per DRG for hospitalizations. Direct medical costs were analyzed from a “payer” perspective, including payments from the public health insurance, private supplementary health insurers, and patients’ co-payment. Significant differences in costs were identified with a Student’s t-test for the means. To calculate incremental cost-effectiveness, the additional cost in the capecitabine arm was divided by the additional years of life saved. The time horizon of the clinical trial was 15 months and cost and health effects were not discounted. RESULTS: Survival was longer in the combination arm (mean 442 days versus 352 days). The cost of capecitabine amounted to €1786, while the cost of docetaxel was significantly reduced in the combination group (€6089 versus €7856; p < 0.0001). None of the other cost components differed between treatment groups, and the overall direct medical cost was comparable in the combination group (€9888 ± 343) and in the monotherapy group (€9852 ± 378; p = 0.9436). The additional cost in the combination arm was €36 and the clinical benefit was 0.23 life-year saved. Thus, the cost per life-year saved ratio was estimated to €157. CONCLUSIONS: Capecitabine/docetaxel combination appears as a highly cost-effective strategy in comparison to docetaxel monotherapy in the treatment of advanced or metastatic breast cancer in France, while these results derived from a randomized clinical trial need to be confirmed in current practice.

SESSION IV
QUALITY OF LIFE OUTCOMES II

OBJECTIVES: The generic Short Form (SF)-36 is one of the most commonly used health status instruments in patients with cerebrovascular disease. However, a responsiveness to change—a pre-requisite for evaluative purposes—has not yet been assessed for neither the SF-36 nor its shortened version, the SF-12. Responsiveness to change describes the ability of health status instruments to detect clinically meaningful changes in HRQoL (health-related quality of life) over time. The main objective of the present study was, therefore, to determine responsiveness to change of the SF-12 questionnaire in patients with stroke and TIA. METHODS: Patients with stroke/TIA were included at admission to one of the four participating hospitals. HRQoL was assessed with the Physical (PCS-12) and Mental (MCS-12) Component Summary scales at baseline and after 12 months. Responsiveness to change was determined with the standardized response mean (SRM) and classified as small (SRM 0.20–0.49), moderate (0.50–0.79) or large (0.80). SRMs were calculated separately for patients after stroke and TIA, and according to stroke severity as measured with the NIH (National Institutes of Health) stroke scale. RESULTS: A total of 558 patients was included (55% men, mean (standard deviation) age 65 (13) years; 45% women, 69 (14) years). Indications for admission were stroke (74%) and TIA (26%). In patients with stroke, SRMs were moderate for both the PCS-12 (SRM 0.5; absolute change –5.9 (12)) and the MCS-12 (SRM 0.5; –6.6 (13)). In patients with TIA, SRMs were below 0.2 for the PCS-12 (absolute change –0.7 (11)) and 0.3 for the MCS-12 (–3.7 (11)). SRMs increased with stroke severity as indicated by the NIH stroke scale score. CONCLUSIONS: The SF-12 summary scales show a moderate responsiveness to change in patients after stroke. Responsiveness to change was higher in patients with increased stroke severity.

OBJECTIVE: The EQ-5D is a standardized, non-disease-specific instrument for describing and valuing patients’ health-related quality of life. The purpose of this study is to evaluate psychometric properties of the EQ-5D in patients with irritable bowel syndrome (IBS).

METHODS: Data from 4 European studies was assessed: 2 studies from the UK (n = 161 and 305 IBS patients), 1 from Spain (n = 517), and 1 from Germany (n = 100). Measures used to examine the EQ-5D included the SF-36, the Irritable Bowel Syndrome—Quality of Life (IBS-QOL) scale, and both subjective and clinical global assessments of IBS. Convergent validity was assessed using SF-36 and IBS-QOL data, discriminate validity using global ratings of severity, and responsiveness by subjective and physician assessment of condition. All sub-
jects were clinically typed into IBS category: constipation, diarrhea or alternating. **RESULTS:** Correlations between the EQ-5D visual analogue scale (EQ VAS) score and the SF-36 subscales (available in the UK studies) were moderate to high ($r = 0.33$ to $0.71$, $p < 0.01$) with lower associations seen with the mental health scores. Correlations with the IBS-QOL (available in all studies) ranged from $0.33$ to $0.54$ ($p < 0.01$). Levels of responses to EQ-5D items and the EQ VAS score were significantly better for control patients than for patients with IBS (all $p < 0.01$). The EQ VAS was able to discriminate between levels of pain severity (quartiles, $p < 0.001$; mild/moderate/severe, $p < 0.05$) and general health severity (mild/moderate/severe, $p < 0.001$). The EQ VAS was responsive in patients with both a self-perceived and physician-rated improvement in condition at 1 year (10.7-pt improvement, effect size and 8.7-pt improvement, ES = 0.47, respectively). **CONCLUSIONS:** The EQ-5D performs quite well in comparison to the SF-36 (general) and IBS-QOL (disease-specific) patient reported outcomes. It is a brief, valid and responsive measure that can used to generate preference-based valuations of health-related quality of life in patients with IBS.

**PREVALENCE AND QUALITY OF LIFE OF PATIENTS SUFFERING FROM RESTLESS LEGS SYNDROME IN FRANCE—INSTANT STUDY**

**OBJECTIVES:** Estimate the prevalence and the quality of life of restless legs syndrome (RLS) in the French population 18 years of age or older. **METHODS:** A population-based survey was conducted among 10,000 adults through face to face interviews by using the quota sampling method (on age, sex, geographical living area, economic working class and woman working status). The screening was made with the 4 International RLS Study Group (IRLSSG) criteria. Quality of life was assessed with the SF-36 questionnaire among subjects suffering from RLS and a control group of 540 subjects randomly selected among the global sample. **RESULTS:** The population surveyed was representative of the French population. The lifetime prevalence of RLS (at least one symptom episode in past life) was estimated: 9.2%, IC 95% = [8.3%; 10.2%]. The annual prevalence of RLS (at least one symptom episode in the past year) was estimated: 8.7%, IC 95% = [7.7%; 9.6%]. Among RLS population, the sex ratio women to men was 2 to 1 and the mean age at the time of the study was 48.5 years versus 46.5 years in the control group. After adjustment on age and sex, all quality of life dimensions were worse in the RLS population than in the control group: Physical Functioning: 82.7 vs. 87.2 ($p < 0.001$); Role Functioning: 74.4 vs. 84.6 ($p < 0.001$); Bodily Pain: 63.7 vs. 75.1 ($p < 0.001$); General Health: 62.7 vs. 69.6 ($p < 0.001$); Vitality: 53.4 vs. 59.6 ($p < 0.001$); Social Functioning: 77.9 vs. 85.2 ($p < 0.001$); Reported Health Transition: 75.0 vs. 84.0 ($p < 0.001$); Mental Health: 62.3 vs. 68.3 ($p < 0.001$). **CONCLUSIONS:** RLS is a frequent disease, it affects 9% of the French adult population. This prevalence is consistent with the findings of studies from other countries. RLS has a significant impact on quality of life, as measured by the SF-36 questionnaire.