**Results:** The data collection sheets were satisfactory instruments to capture trial related workload data. From the data gathered it was possible to determine and establish mean task times for a number of trial activities. These parameters also provided a platform for identifying factors that should be taken into account when developing a clinical trial budget for an investigative site. Data of professional training, tertiary education and professional experience of trial staff has been reported for the participating sites.
**Conclusions:** This study provides insight into the time requirements involved in undertaking recognized clinical trial tasks for a specific colorectal study in Australia. It also identifies some less recognized workload issues which should be taken into account when assessing workload and budgets for clinical trials. Undertaking a study of this nature has been challenging and highlights the need for a more research into the issues of clinical trial workload to be undertaken in order to establish industry benchmarks.

**4218** POSTER

**Determining the minimal clinically important difference for health related quality of life scores from the EORTC QLQ-C30 in lung cancer patients: an analysis of pooled data**

J. Maringwa[1], C. Coens[1], C. Quinten[1], F. Martinelli[1], C. Gotay[2], M. King[3], D. Osaba[4], J. Ringash[5], A. Bottomley[1]. *[1]EORTC, Quality of Life, Brussels, Belgium; [2]University of British Columbia, Primary Prevention School of Population and Public Health, Vancouver, Canada; [3]University of Sydney, Psycho-oncology Co-operative Research Group, Sydney, Australia; [4]Quality of Life Consulting, Quality of Life, Vancouver, Canada; [5]University of Toronto, The Princess Margaret Hospital, Toronto, Canada*

**Background:** Patient assessment of Health Related Quality of Life (HRQOL) in cancer clinical trials has increased over the years. However, understanding the clinical meaning of HRQOL scores requires further investigation. The objective is to determine changes in HRQOL scores on the EORTC QLQ-C30 scales (with range 0–100) which correspond to the minimal clinically important difference (MCID).
**Materials and Methods:** Two closed European Organization for Research and Treatment of Cancer (EORTC) randomized controlled trials enrolling in total 812 advanced NSCLC cancer patients were jointly analyzed. WHO performance status (PS) was chosen as a clinical anchor for 6 HRQOL scales of the QLQ-C30 questionnaire; physical (PF), social (SF) and role (RF) functioning, global health status (GH), fatigue (FA) and pain (PA). Estimates of the MCID for the scales were calculated using a combination of an anchor and distribution-based approach. Changes in clinical anchor were categorized into 3 groups; improvement, no change and deterioration. Analysis of variance was used to compare HRQOL scores across groups. The differences in the mean of HRQOL score changes between adjacent groups and effect size (difference divided by standard deviation at baseline) were calculated. Adjacent group differences corresponding to an effect size of at least 0.20 were used to estimate the MCID.
**Results:** 485 patients who had both HRQOL and PS scores on at least 2 time points (baseline and on/after treatment) were included, and the 2 available most separated time points were chosen for analysis. Significant differences ($p < 0.05$) in HRQOL across groups were noted for all 6 scales. The ranges of adjacent group differences and effect sizes (>0.20) were; PF (6.1−9.9; 0.25−0.41), SF (7.7; 0.27), RF (10.9−12.3; 0.31−0.35), GH (10.2; 0.46), FA (5.9−15.7; 0.22−0.60) and PA (14.8; 0.47). The results suggest the following estimates (mean) of the MCID; PF: 6, SF: 8, RF: 11, GH: 10, FA: 6 and PA: 15.
**Conclusions:** Our results suggest that in patients with advanced NSCLC undergoing treatment, the functioning, global health status and fatigue scales can be interpreted using a change in score of 6 to 11 as the MCID (on scales with range 0–100). For pain, a relatively higher MCID estimate of 15 was found. These MCID estimates can be used to classify patients by changes in HRQOL and symptoms over time as well as to aid sample size determination for future studies. Further validation in cancer patients with other diagnoses is planned.

**4219** POSTER

**Information needs of patients with cancer considering participation phase I trials**

D. van der Biessen[1]. *[1]ErasmusMC Daniel, Medical Oncology Research Centre, Rotterdam, The Netherlands*

**Background:** Improvement of cancer treatment is achieved by clinical trials. Patients with solid tumours with no standard treatment options may consider participation in phase I trials. Hope on a miracle is in many cases the reason for participation. Lack of knowledge about the purpose of a phase I trial can be a major obstacle for ethical informed consent. A study was performed to investigate the information that can motivate patients in the first three stages of the model of Prochaska and DiClemente considering participation of a phase I trial at the ErasmusMC Daniel, Rotterdam.
**Materials and Methods:** A qualitative study was performed with semi-structured interviews using a topic list. The topic list was based on literature research concerning cancer patients' information needs. The Delphi method was used to define the list. Twelve interviews were taken from eight patients, four men and four women at the age of 36 to 71 years old. The verbatim interviews were evaluated using a qualitative database program Kwalitan.
**Results:** During the first three stages of the model of Prochaska and DiClemente, precontemplation, contemplation and preparation, the patients' information needs change. At precontemplation, the patient is informed about the lack of treatment options and needs information concerning the possibilities to participate in clinical trials. The attitude and the oral information given by the physician and/or nurses add to the decision making during contemplation. All patients found the written information too long and half of them did not understand this information. During preparation, control over informed consent is important for patients.
**Conclusions:** In the first three stages of the model of Prochaska en DiClemente patients with solid tumours with no standard treatment options need open, honest, understandable information. This information should be provided in an emphatic way, with an eye for the patients' needs, problems and backgrounds. Thus patients are better prepared to make a well-advised decision whether or not to participate in a phase I trial.

**4220** POSTER

**Teenager and young adult cancer care – A grounded theory study of network-focused nursing**

P.R. Olsen[1], I. Harder[2]. *[1]Aarhus University Hospital, Department of Oncology, Aarhus C, Denmark; [2]University of Aarhus Faculty of Health Sciences, Department of Nursing Science, Aarhus C, Denmark*

**Background:** Several research findings identify social network and support systems as important aspects in the rehabilitation and coping processes of teenagers and young adults (TYAs) with cancer and their parents. However, there is little empirical knowledge of how nurses can support TYAs and their social network. Research in this area has not been done nationally, and is limited internationally.
At an oncological youth unit in Denmark nurses have developed a systematic intervention programme in caring for TYAs with cancer and their significant others (parents and on rare occasions a partner). Nursing activities are directed towards interactions intending to help the TYAs and their significant others in maintaining contact with a supportive social network.
**Study purpose:** To generate a substantive theory that explains what happens when oncology nurses interact with TYAs with cancer and their significant others in order to support them in preserving, establishing, and strengthening family relationships and social network during the treatment period.
**Material and Methods:** The qualitative research method Grounded Theory guided the study (Glaser and Strauss 1967, Charmaz 2006).
Sources of data:
1. 7 nurses working in the Youth Unit, Department of Oncology, Aarhus University Hospital,
2. 12 TYAs with cancer aged 15−22 who had been or were being treated in the unit, and
3. 19 parents or partners were included in the study.

Data were collected through in-depth interviews, participant observation, informal conversations and documents.
**Findings:** A basic social process of C*reating a space* for teenagers' and young adults' normal growth and development was the nurses' main challenge.
*Bridging* was defined as the core concept in nurses' strategies. By strategies of: '*Tuning in*', '*Framing the situation*', '*Navigating towards the goal*', '*Connecting people*', the nurses worked at reaching into the private sphere, extending beyond family centred care and including the wider social network. The nurses had to earn their way into this private world.
**Conclusions:** Nurses worked proactively to preserve social integration of the patient and the significant others and to provide conditions for including the wider social network. Establishing a trustful and respectful partnership with an emerging independent young adult and his or her family requires a highly sensitive approach, careful assessment and cooperation. Findings of this study show how this can be accomplished and can inspire nurses to improve care of TYAs with cancer – an area of nursing that needs to develop internationally.