programs for both the patients and their family members should be employed.

Table 1

	PFr	RPr	BPr	GHr	VTr	SFr	REr	MHr	PCSr	MCSr
PF	**	**	**	NS	**	**	NS	**	NS	*
RP	NS	NS	NS	NS	*	**	NS	*	NS	**
BP	**	*	**	*	NS	*	NS	*	NS	NS
GH	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
DVT	**	NS	NS	NS	NS	NS	NS	NS	NS	NS
SF	NS	NS	NS	NS	**	**	NS	*	NS	*
RE	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS
MH	NS	NS	NS	NS	NS	*	NS	NS	NS	NS
PCS	**	**	**	*	**	**	NS	**	*	*
MCS	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

r = relatives, * = 0.05, ** = 0.01. NS = Not Significant.

3052 POSTER

Biosimilar filgrastim is an effective primary prophylactic therapy for neutropenia in patients (pts) receiving doxorubicin and docetaxel (AT) for breast cancer (BC)

C.F. Waller[1], V.F. Semiglazov[2], S. Chan[3], R. Challand[4]. *[1]Freiburg University Medical Center, Department of Haematology/Oncology, Freiburg, Germany; [2]N.N. Petrov Research Institute of Oncology, Breast Tumor Department, Saint Petersburg, Russian Federation; [3]Nottingham University Hospital NHS Trust, Oncology Department, Nottingham, United Kingdom; [4]Hospira, Oncology, Leamington Spa, United Kingdom*

Background: Recombinant granulocyte colony-stimulating factor (filgrastim; Neupogen®, Amgen) is integral to supportive care for pts receiving myelosuppressive chemotherapy. Hospira has developed a biosimilar filgrastim, Hospira filgrastim, which has been evaluated in preclinical and clinical studies. Here we report the results of a phase III, randomised, double-blind, therapeutic equivalence study to evaluate the efficacy, safety and tolerability of Hospira filgrastim versus Neupogen in pts receiving AT for BC (GCF071).
Materials and Methods: Female pts with BC suitable for (neo)adjuvant or first-line treatment with AT were randomised (2:1) to receive a subcutaneous injection of 5 μg/kg Hospira filgrastim or 5 μg/kg Neupogen once daily until the documented absolute neutrophil count (ANC) nadir had passed and ANC was $>3\times10^9$/L or for a maximum of 14 days. Up to 6 cycles of Hospira filgrastim or Neupogen were given at 3-weekly intervals.
Results: 279 pts from 37 centres in 10 countries were randomised: 184 to receive Hospira filgrastim and 95 to receive Neupogen. One pt from the Hospira filgrastim group withdrew consent and did not receive study medication. The mean number of injections in cycles 1–6 was similar in the two groups: 42.0 for Hospira filgrastim and 41.9 for Neupogen. The confidence interval for the difference in duration of severe neutropenia (DSN) in cycle 1 between Hospira filgrastim and Neupogen (primary endpoint) was within the predefined range and demonstrated equivalence of the two agents (DSN = 1.85 days and 1.47 days for each drug respectively). Incidence of severe neutropenia in cycle 1 was similar for Hospira filgrastim (77.6%) and Neupogen (68.2%). In cycle 1, mean time to ANC recovery was 7.8 days for both groups. Incidence of febrile neutropenia (FN) over cycles 1–3 was 2.4% for both treatments, and incidence of hospitalisation due to FN was similarly low at 2.1% in each group. Incidence of treatment-related adverse events (TRAEs) was similar (24.6% for Hospira filgrastim, 23.2% for Neupogen). Consistent with previous studies of filgrastim, the most common TRAE was bone pain.
Conclusions: Hospira filgrastim was equivalent to Neupogen for all parameters tested. These included short DSN and low rates of FN in pts receiving cytotoxic chemotherapy. Hospira filgrastim may provide an effective alternative to Neupogen for the primary prophylaxis of neutropenia.

3053 POSTER

Management of anaemia in oncology: use and efficacy of Darbepoetin alfa in CIA patients

B. Levache[1], B. Sousselier[1], L. Cany[1], C. Maguire[2], F. Saillour-Glenisson[3], F. Fagnani[4]. *[1]Polyclinique Francheville, Oncology Unit, Perigueux, France; [2]Polyclinique Francheville, Clinical Research Unit, Perigueux, France; [3]CHU Bordeaux, Evaluation Qlinique et Qualité, Perigueux, France; [4]CEMKA-EVAL, Pharmaco-Economics Department, Paris, France*

Objectives: To assess the management of chemotherapy-induced anaemia with ESAs, and to evaluate the place of RBC transfusions.
Methodology: A retrospective observational study was conducted in a single center (Francheville Polyclinic, Périgueux), with a register of 1153 cancer patients treated with chemotherapy from July 2006 to March 2008. This period coincided with implementation of a protocol for treating anaemia in the unit. RBC transfusions and the use of Darbepoetin alfa (DA, Aranesp®) were recorded as well as associated haemoglobin (Hb) levels. The choice of DA was justified by the Q3W schedule (once every 3 weeks) which enabled synchronisation with chemotherapy protocols. The efficacy of treatment was defined according to increase in Hb levels after 3 successive injections.
Results: Of the total group of 1153 patients, 325 (28.1%) were treated for anaemia with DA (72% received 500 μg Q3W). 90.1% of patients presented solid tumours (breast, lung and colorectal representing 40% of the total). The cumulative number of delivered chemotherapy cycles was 392.
127 of 325 patients (39.1%) had at least one transfusion during the study (cumulative number: 352 transfusions), 76.7% of evaluable patients (N = 214) responded to treatment after 3 or even 2 consecutive DA injections. The improvements in Hb levels over successive DA injections were greater in the patients with initially low Hb levels. After DA treatment, 80% of patients presented an Hb level between 10−12 g/dL, according with the new EMEA recommendations. In 27.3% of cases, patients had previously received RBC transfusion before receiving DA. Use of DA as anaemia treatment in this unit showed a progressive reduction of the transfusion number.
Conclusion: clinical practice in this centre seems to be consistent with recommendations from health authorities concerning the management of chemotherapy-induced anaemia and the efficacy results for darbepoetin alfa are similar to those provided in clinical studies. It has been suggested that darbepoetin alfa could act as an optional treatment, and it would be interesting to consider it in medical-economic studies. The great complexity of descriptive analyses of oncology and anaemia practices, taking into account the multiplicity of clinical situations, follow-up durations and disease managements, must be highlighted; therefore a prospective study has been implemented in this unit to fill out this analysis.

3054 POSTER

An analytical web portal for estimation of survival in cancer patients receiving standard antineoplastic treatments

N. Knud Mejer[1], G. Torben Gøth[2], N. Dorte Nielsen[1], D. Gedske Daugaard[2]. *[1]Herlev University Hospital, Clinical Research Unit, Herlev, Denmark; [2]Rigshospitalet University Hospital of Copenhagen, Clinical Research Unit, Copenhagen, Denmark*

Background: Documentation of standard treatment quality is important in order to perform a proper in-formation of the patient and to compare own data with the best international standard. When part of a clinical trial is introduced as a new standard treatment in daily clinic, the in- and ex-clusion criteria often change and the patient group is no longer a well defined population with respect to inclusion criteria. This may change survival data as compared to the survival in the clinical study. Therefore, survival on all standard treatments should be followed as part of a department's quality control.
We have created "The Analytic Web Portal (AWP)", a web application intended to provide an integrated environment for data analysis and visualization. The system offers two statistical procedures: survival time analysis and response rates to cancer treatments.
Materials and Methods: The system consists of two parts: A data integration part and a data analysis part. The data integration part deals with data collection, filtering treatment data based on a specified format, and saved in a data storage. This is done by the use of data ware-house technology. Patient treatment data are extracted from a hospital application and merged with death data from a centralized governmental data registry. The analytical part deals with statistical calculations and presentation of results.
All the statistical processing in AWP was derived from SPSS algorithms and cross checks were made to confirm the validity of the generated results from AWP.