Primary
- To describe the HCRU in hospitalized FN patients treated with chemotherapy for solid tumors and hematological malignancies in Bulgaria as observed in clinical practice.

Secondary
- To define the characteristics of the patient population (prior to hospitalization) in terms of EOCG performance status, stage disease, comorbidities, chemotherapy risk level of FN (as per EORTC 2010 guidelines), gender and country.
- To describe chemotherapy treatment patterns (type of chemotherapy, number of cycles received, completion of planned treatment, reason for treatment discontinuation) and G-CSF patients (no. days received, primary/secondary prophylaxis or treatment).

STUDY DESIGN
- This was a multicenter, retrospective, observational, non-interventional study based on a cohort chart review. Eligible patients were selected on a consecutive basis starting with the most recent (i.e. patients who completed their chemotherapy by September 2012). The study was conducted without any study specific change to the clinical management of patients.
- Adult patients (≥18 years) diagnosed with solid tumors or hematological malignancies at any stage and ECOG performance status, who were admitted to hospitals and experienced at least one confirmed FN event were enrolled in the study.
- Observation started at the beginning of the cycle in which the first FN occurred (index cycle) until the end of patients respective regimen of chemotherapy treatment or until the patient died or was lost to follow-up.
- HCRU data were summarized for index cycle and post-index cycles (subsequent cycles cumulatively), and overall observation period; while using hospital admission data, neutropenia complications were identified on the basis of hospital admissions with a primary diagnosis related to chemotherapy and was identical for patients with solid tumors and hematological malignancies.
- FN was defined as an absolute neutrophil count (ANC) of <0.5 × 10^9/L or ≤1.0 × 10^9/L predicted to fall below 0.5 × 10^9/L within 48 h, with fever or clinical signs of sepsis (infection). Fever was defined per hospital diagnosis.

METHODS
- FN-specific HCRU parameters included infection prophylaxis and treatments, G-CSF use, other prophylactic medication, interventions and investigations, and FN-related hospitalizations were analyzed.
- G-CSF use groups were defined as primary prophylaxis, secondary prophylaxis or treatment according to the value entered in the setting field on the eCRF G-CSF page. G-CSF use groups were defined as primary prophylaxis, secondary prophylaxis or treatment depending on the patient’s current status of neutropenia.

RESULTS
- In total, 156 patients with solid tumors and hematological malignancies hospitalized for FN in the period of January 2009 to September 2012 from 11 Bulgarian centers were enrolled into this study and included in FAS; 64 (41%) patients had solid tumors, and 92 (59%) patients had hematological malignancies.
- The mean length of FN-related hospitalization was 7.2 days (95% CI 6.7-7.6).
- The majority of patients received G-CSF as treatment and not as a prophylaxis.
- Use of G-CSF as primary prophylaxis was higher in patients with hematological malignancies than with solid tumors; while G-CSF use was greatly reduced in post-index cycles compared to the index cycle (~22% of patients).

The results of this observational study indicate a considerable usage of healthcare resources in chemotherapy cycles in patients experiencing FN in Bulgaria; at the mean length of FN-related hospitalization was 7.2 days; frequent lack of G-CSF prophylaxis particularly in patients with solid tumors was observed; improved G-CSF targeting may reduce FN and lower associated HCRU.

CONCLUSIONS
- The total number of patients, who completed their chemotherapy regimen as planned was 104 patients (67%).
- ADRs:
  - No patients from Bulgaria experienced ADRs related to Aman product.
  - Deaths:
    - The total number of deaths during the retrospective observation period was 17 (11%).
    - The majority of patients who died was equal between the tumor types.
    - The main reasons for death were FN-related, 8 (47%), or cancer-related, 9 (53%), the latter of which were FN-related.

- The percentage of patients who died was equal between the tumor types; while FN-related hospitalizations were described. as pulmonary and cardiovascular mortality insufficiently esap, atrial fibrillation, and suspected brain hemorrhage, due to poor chemotherapy thrombocytopenia (1 patients (10%) from each reason).
- The number of patients who died was based on the number of patients who died.

Study Limitations
- Due to the retrospective nature of the study, investigators had to rely on the data for important outcomes to be mutually and accurately collected in medical records, which may not always be the case, potentially introducing underestimation of these outcomes.

REFERENCES