	1st line (n = 100)		Total (n = 133)
	Baseline	Score variation	Score variation
Functional scale			
Social functioning	80.4±23.8	−7.9±29.1	−6.3±28.9
Role functioning	77.8±28.0	−5.6±31.6	−4.7±29.4
Physical functioning	84.9±16.5	−4.2±18.1	−3.8±18.5
Cognitive functioning	86.5±19.8	−1±22.5	−0.8±20.4
Emotional functioning	74.9±22.2	+1±26.5	+1.5±25.5
Symptom scale			
Insomnia	26.5±32.6	−6.1±30.3	−4.8±30.3
Constipation	20.3±29.5	−2.4±37.7	−3.4±34.8
Appetite loss	18.6±26.3	0±34.4	−2.3±33.3
Pain	16.7±2.5	−1.3±30.9	−0.6±31.1
Fatigue	31.2±25.1	2±25.9	+1.3±25.7
Diarrhea	16.5±24.5	2±29.7	+2.3±30.0
Nausea and vomiting	9.1±20.8	2.4±26.3	+3±23.8
Dyspnea	13.1±22.9	3.1±24.1	+4.6±23.8
Financial difficulties	8.2±20.9	0.7±20.3	+0.5±20.7
Global health status/QoL	**66±20.4**	**−2.5±25.6**	**−1.6±24.6**

6113 POSTER

Efficacy and Safety at 12 Months of 1st Line Bevacizumab (Bv) Plus Chemotherapy (CT) in Elderly Patients (Pt) With Metastatic Colorectal Cancer (mCRC) in Daily Clinical Practice − the CONCERT French Observational Cohort Study

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Background: There are limited data on treatment outcomes in the growing population of elderly patients with mCRC. Elderly patients are often underrepresented in randomized oncology clinical trials. We investigated the efficacy and safety of 1st line Bv combined with various CT in elderly patients subgroups (⩾70 yrs and ⩾75 yrs) with mCRC in the CONCERT cohort study.
Patients and Methods: This prospective, multicenter, non-interventional study assessed pts with mCRC initiating a treatment with Bv and CT (all lines) in daily medical practice in France followed-up for 36 months. We analyzed patients' demographics, treatment patterns, safety, progression free survival (PFS), overall survival (OS) in three subgroups: <70 yrs, ⩾70 yrs and ⩾75 yrs.
Results: Of the 515 patients treated in 1st line in the CONCERT study, 328 pts were ⩾70 yrs (including 91 pts ⩾75 yrs). At baseline, 14.3% of pts in the ⩾75 yrs group had poor ECOG PS (⩾2) vs. 7.4% in the ⩾70 yrs; 70.3% pts ⩾75 yrs vs. 52.1% in the <70 yrs group. Co-morbidities were reported in 69.0% of pts ⩾70 yrs; 70.3% pts ⩾75 yrs vs. 52.1% in the <70 yrs group. Median PFS (months) was 11.4, 95% CI [10.0; 12.3] <70 yrs group; 10.0, 95% CI [8.9; 11.8] ⩾70 yrs group and 9.5, 95% CI [7.9; 11.3]) ⩾75 yrs group. Median OS was not reached in the 3 subgroups. The incidence of Bv-related adverse events (AEs) was 56.3% in the ⩾75 yrs group, 53.9% in the ⩾70 yrs group and 52.8% in the <70 yrs group.
Incidence of main Bv-targeted AEs per age group is shown in the table.

	<70 yrs (n = 299)	⩾70 yrs (n = 178)	⩾75 yrs (n = 87)
Related AEs	52.8%	53.9%	56.3%
Grade 3/4 AEs	8.7%	11.2%	11.5%
Targeted AEs (all grades)	51.2%	52.2%	56.3%
Bleeding	25.1%	19.7%	20.7%
Proteinuria	15.1%	16.9%	21.8%
Hypertension	13.4%	16.9%	20.7%
Neutropenia	9.7%	12.4%	13.8%
Venous thromboembolic events	3.3%	6.2%	9.2%
Wound healing disorder	3.3%	2.8%	3.4%
Fistula	2.3%	2.8%	2.3%

Hypertension, proteinuria, venous thromboembolic events and neutropenia were more common in older than in younger patients. No treatment-related death was reported across all age groups at 12 months.
Conclusion: Results of this prospective cohort study suggest that the efficacy of 1st line treatment with Bv and CT is independent of age and is tolerable in elderly patients with mCRC.

6114 POSTER

Clinical Outcomes of Bevacizumab (BV) + XELOX Combination for the First-line Treatment of Patients (pts) With Advanced Cancer of the Colon or Rectum (ACRC) − Preliminary Results of the OBELIX Study

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Background: BV, an anti-vascular endothelial growth factor antibody, when combined with other chemotherapeutic drugs, prolongs OS and PFS in ACRC patients. Several phase IV and observational studies provide information on the clinical outcome of the BV-treated pts in large cohorts. We conducted a multicentric, open-label, single arm, non-comparative study to confirm these results in a general Italian population of patients with ACRC.
Materials and Methods: Previously untreated pts with histologically confirmed ACRC receiving XELOX (Capecitabine 1000 mg/m^2 bid for 14 days + Oxaliplatin 130 mg/m^2 d1, q3w) for 8 courses + BV (7.5 mg/kg, d1, q3w) until disease progression, death, or unacceptable toxicities were enrolled. The primary end-point was progression free survival (PFS). Secondary were safety, RR, OS, percentage of R0 resectability and QoL of patients.
Results: 205 assessable patients were enrolled between Feb 2008 and Nov 2009 (male 56%; median age 64 yrs range 34−80). All of pts resulted with an ECOG PS 0−1. 104 pts (51%) had metastases confined in 1 site (41% liver only, 10% lung only). Pts received 7 courses of XELOX (range 1−13) and 8 courses of BV (range 1−34). Median PFS was 10.26 months (95% CI 8.79–11.21) and median OS reached 21.31 months (95% CI 19.93–not reached); best ORR was 43% with a clinical benefit of 73% and a median duration of response.of 9.8 months (range 7.9–10.8). 26 pts (13%) underwent liver surgery of whom 12% had a R0/R1 resection. 102 pts (49.8%) experienced a G3−4 adverse events.
Conclusion: OBELIX study shows efficacy data of Bevacizumab administered in first line ACRC in the Italian clinical practice consistent with those observed in prospective randomized clinical trials and other large observational studies.

6115 POSTER

Modelling Tumour Kinetics Including Early Response, Tumour Nadir and Progression During First-line Chemotherapy of Metastatic Colorectal Cancer (mCRC)

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Background: Recently, Piesseveaux et al. (Ann. Oncol 2009 20(8): 1375–1382) proposed to use a relative early decrease of tumour size of 20% in first-line therapy for mCRC as a predictor for clinically relevant outcomes (TTP and OS). This method is based on heuristics and not on theoretical considerations. In the present investigation, we deloped a model with the ability to predict individual tumour size kinetics.
Material and Methods: Based on the data of two randomized trials, the FIRE-1 (n = 479) and the CIOX (n = 185) study, we developed a mathematical model which allowed to formulate non-linear U-shaped individual relationships between time and tumour size. This model provides a simple method to capture tumour load at baseline and its decrease to evaluate their impact on TTP and OS by Cox proportional hazard regression. This formal approach allows deriving prediction rules and helps to define a practical way to apply them to patients: how to schedule early