

INDEPENDENT ETHICS COMMITTEE

Established in 1973, the institutional Independent Ethics Committee reviews all new clinical studies submitted by investigators and approved by the Scientific Review Board. In May 2010, the Committee was renewed.

In 2010, 76 new clinical studies received their ethical approval. The median time from submission to discussion was 25 days, a result obtained thanks to monthly meetings of the Committee and an optimized pathway for study clearance, which is carried out in close cooperation with all other relevant institutional bodies (General and Legal Affairs Unit, Economic and Financial Resource Management Unit, and the Pharmacy). This tight interinstitutional collaboration results in an efficient streamlining of the various scientific and administrative components of the ethical review process.

In 2010, the Independent Ethics Committee maintained its focus on tissue "donation" for biobanking. The concept of a donation was initially formalized by the Ethics Committee in a general statement and then submitted for discussion to experts from different disciplines, including law, ethics and privacy, as well as patient representatives. A consensus document was published, and was presented with an ad-hoc public event organized in parallel with the 2010 Congress of the European Society for Medical Oncology. At present, a new draft informed consent for all institutional patients is under construction, with a view to sharing it with the national authority on privacy protection.

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ONGOING CLINICAL STUDIES

Breast Carcinoma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
98/01	Celio L.	1998	III	24	Closed accrual

Randomized double-blind trial in postmenopausal women with primary breast cancer who have received adjuvant tamoxifen for 2-3 years, comparing subsequent adjuvant exemestane treatment with further tamoxifen

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
99/02	Bajetta E.	1999	III	72	Closed accrual

A phase III study to evaluate letrozole as adjuvant endocrine therapy for postmenopausal women with receptor(ER and/or PgR) positive tumor

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
02/03	Gianni L.	2002	III	35	Closed accrual

A multicenter, randomized, controlled open-labeled trial of paclitaxel-containing chemotherapy (AT&T) followed by CMF versus the same chemotherapy plus Herceptin in women with locally advanced breast cancer and HER2/C-ERBB2 overexpression and amplification, with a parallel observational study of the same chemotherapy regimen alone, in patients with HER2 negative tumors (or 1+ by immunohistochemistry)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
03/32	Berrino F.	2003	Observational	2290	256

Prognostic significance of blood concentrations of testosterone and insulin in women with early breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
04/06	Gianni A.M.	2004	Pilot	4	2

Immunization of patients with locally advanced/metastatic breast and ovary cancer with autologous monocyte-derived dendritic cells loaded with apoptotic/necrotic autologous tumor cells exposed to heat shock

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/39	Nava M.	2005	III	377	35

Prevention of capsule formation around prosthesis under the pectoralis major muscle, in breast reconstruction, by one local application of mitomycin-C

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/68	Gianni L.	2006	II	7	Closed accrual

A phase II, single arm, multicenter study to evaluate the efficacy and safety of the combination of Omnitarg and Herceptin in patients with HER2-positive metastatic breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
06/39	Gianni L.	2006	III	14	Closed accrual

A randomized, open-label, 2-arm, multicentre, phase III study to evaluate the efficacy and safety of bevacizumab in combination with Trastuzumab/Docetaxel compared with Trastuzumab/Docetaxel alone as first line treatment for patients with HER-2 positive locally recurrent or metastatic breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/04	Gianni L.	2007	II	8	Closed accrual

A randomized, double-blind, phase II trial of Fulvestran plus Enzastaurin versus Fulvestran plus Placebo in aromatase inhibitor resistant metastatic breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/24	Nava M.	2008	II	36	

Prevention of postoperative pain by using botulinic toxin in patients candidates to mastectomy and immediate reconstruction with expander and in patients candidates to additive contralateral mastoplastic in the second reconstructive phase

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/37	Berrino F.	2007	-	250	

Randomized trial of diet, physical activity and breast cancer recurrences: the DIANA-5 study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/43	Gianni L.	2007	IIb	26	2

A multinational double-blind, randomized phase IIb cooperative group study evaluating the efficacy and safety of sorafenib compared to placebo when administered in combination with chemotherapy and/or endocrine therapy in patients with locally recurrent or metastatic breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/47	Gianni L.	2007	II	28	Closed accrual

A randomized multicentric international phase II study of Herceptin® and docetaxel versus docetaxel in association with Omnitarg™ and Herceptin® versus Omnitarg™ and Herceptin® in the treatment of locally advanced HER-2 positive breast cancer, inflammatory or early breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/65	Manoukian S., Vergnaghi D., Bergonzi S.	2008	Observational	106	6

Italian ISS network for the surveillance of women at high breast cancer risk (ISSIN-HIBCR)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/18	Gianni L.	2008	II	319	117

Phase II study. Safety of the scheme of adjuvant or primary sequential chemotherapy in operable breast cancer at high risk (AT x 3 - CMF x 3)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/65	Gianni L.	2009	II	5	Closed accrual

A randomized, multicenter, phase II study of the efficacy and safety of trastuzumab-MCC-DM1 vs trastuzumab (Herceptin) and Docetaxel (Taxotere) in patients with metastatic HER2-positive breast cancer who have not received prior chemotherapy for metastatic disease

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/76	Berrino F.	2010	III	80	80

Tevere project: primary prevention of breast cancer by diet, physical activity or Metformin assumption

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/07	Gianni A.M.	2009	II	29	15

Phase II study to evaluate the efficacy and tolerability of sorafenib in treatment of post-surgical and post-radiotherapy edema of the upper limb in subjects affected with breast neoplasms

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/16	Gianni L.	2009	III	5	3

A randomized, multicenter, phase III open-label study of the efficacy and safety of trastuzumab-MCC-DM1 vs capecitabine-lapatinib in patients with HER2-positive locally advanced or metastatic breast cancer who have received prior trastuzumab-based therapy

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/18	Gianni L.	2009	II	2	Closed accrual

A phase Ib/II, open-label study of the safety, tolerability and efficacy of trastuzumab-MCC-DM1 in combination with pertuzumab administered intravenously to patients with HER2 positive locally advanced or metastatic breast cancer who have previously received trastuzumab

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/33	Gianni L.	2010	Ib	2	2

A phase Ib, open label, dose escalation study of the safety and pharmacology of P13-kinase inhibitor GDC-0941 in combination with paclitaxel and bevacizumab in patients with locally recurrent or metastatic breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/63	Gianni L.	2010	III	4	4

A randomized phase III, double-blind, placebo-controlled multicenter trial of daily everolimus in combination with trastuzumab and vinorelbine, in pretreated women with HER2/neu over-expressing locally advanced or metastatic breast cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/67	Gianni L.	2010	II	8	8

Multicenter, randomized, open label study evaluating a poly(AFP-ribosio) polymerase-1(PARP-1) inhibitor, SAR240550 (BSI-201), administered twice weekly or weekly, in combination with gemcitabine/carboplatin, in patients with Triple Negative breast Cancer (mTNBC)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/68	Raspagliesi F.	2010	III	1	1

A multi-centre, open-label, randomized, two arm phase III trial of bevacizumab plus chemotherapy versus chemotherapy alone in patients with platinum-resistant, epithelial ovarian, fallopian tube or primary peritoneal cancer

Gastrointestinal Cancers

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
04/17	Casali P.	2005	II	22	Closed accrual

A phase II, open-label study of PTK787/ZK222584 in the treatment of metastatic gastrointestinal stromal tumors (GISTs) resistant to imatinib mesylate

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
04/28	Bajetta E.	2005	III	71	
Open-label randomized, multicenter phase III study of adjuvant chemotherapy in radically resected adenocarcinoma of the stomach or gastroesophageal junction: comparison of sequential treatment (CPT11 + 5-FU/LV TXT + CDDP versus a 5-FU/LV regimen)					
05/11	Casali P.	2005	III	36	Closed accrual
Localized, completely resected, gastrointestinal stromal tumors (GIST) expressing KIT receptor: a controlled randomized trial on adjuvant imatinib mesylate (Glivec) versus no further therapy after complete surgery					
05/19	Casali P.	2005	II	25	Closed accrual
A treatment protocol for patients with gastrointestinal stromal tumor who are ineligible for participation in other SU011248 protocols and are refractory to or intolerant of imatinib mesylate					
05/27	Bajetta E.	2005	II	55	Closed accrual
Randomized phase II trial testing the efficacy of three bevacizumab-containing first-line regimen from metastatic colorectal cancer					
05/33	Buzzoni R.	2005	III	38	Closed accrual
A randomized, three arm multinational phase III study to investigate bevacizumab (q3w r q2w) in combination with either intermittent capecitabine plus oxaliplatin (Xelox) (q3w) or fluorouracil/leucovorin with oxaliplatin (Folfox-4) versus Folfox-4 regimen alone as adjuvant chemotherapy in colon carcinoma: the AVANT study					
05/37	Casali P.	2005	I	11	Closed accrual
A phase I multicenter, dose escalation study of AMN107 in combination with imatinib on a continuous daily dosing schedule in adult patients with imatinib-resistant gastrointestinal stromal tumors (GIST)					
05/49	Bajetta E.	2005	II	39	Closed accrual
Capecitabine time table and radiotherapy in the adjuvant treatment of cancer of the rectum					
06/24	Gavazzi C.	2006	III	83	18
Home enteral nutrition in malnourished patients after major surgery for gastrointestinal malignancy					
06/27	Buzzoni R.	2006	II	3	Closed accrual
An open-label, stratified, single-arm phase II study of RADO01 in patients with advanced pancreatic neuroendocrine tumor (NET) after failure of cytotoxic chemotherapy					
06/54	Bajetta E.	2006	III	1	Closed accrual
Phase III, randomized, double-blind, stratified, comparative, placebo controlled, parallel group, multicentre study to assess the effect of deep subcutaneous injections of lanreotide autogel 120 mg administered every 28 days on tumour progression free survival in patients with non functioning entero-pancreatic endocrine tumour					
06/56	Casali P.	2006	-	13	Closed accrual
A treatment protocol for patients continuing from a prior SU011248 protocol					
06/75	Mazzaferro V.	2006	II	39	Closed accrual
A prospective randomized, open-label trial comparing Sirolimus-containing versus mTOR-inhibitor-free immunosuppression in patients undergoing liver transplantation for hepatocellular carcinoma					
07/09	Regalia E.	2007	-	54	Closed accrual
LIVER MATCH. An Italian multicentric study to evaluate the impact of donor-recipient matching in the outcome of liver transplantation at short, medium and long term					

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/25	Casali P.	2007	Observational	36	Closed accrual

A study of the genetic polymorphisms of patients with gastrointestinal stromal tumors (GIST) and of their predictive value of clinical activity of tyrosin kinase inhibitors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/32	Casali P.	2007	Observational	54	4

The global observational registry collecting longitudinal data on advanced GIST patients (GOLD reGISTry)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/52	Bajetta E.	2007	III	88	26

A randomized trial investigating the role of FOLFOX-4 regimen duration (3 versus 6 months) and bevacizumab as adjuvant therapy for patients with stage II/III colon cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/60	Di Bartolomeo M.	2008(31/03/10)	II	18	

A double-blind, randomized, placebo-controlled, phase II study of enzastaurin with 5-FULV plus bevacizumab as maintenance regimen following fist-line therapy for metastatic colorectal cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/61	Di Bartolomeo M.	2008	III	13	Closed accrual

A multinational, randomized, double-blind study, comparing the efficacy of aflibercept once every 2 weeks versus placebo in patients with metastatic colorectal cancer (MCR) treated with irinotecan/5-FU combination (FOLFIRI) after failure of an oxaliplatin based regimen

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/69	Di Bartolomeo M.	2007	III	9	Closed accrual

A double-blind, randomized, multicenter, phase III study of bevacizumab in combination with capecitabine and cisplatin versus placebo in combination with capecitabine and cisplatin, as first-line therapy in patients with advanced gastric cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/08	Dragani T. Leo E.	2008	-	725	378

Accrual of patients with colorectal cancer and of healthy sisters/brothers for studies on genetic risk factors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/16	Leo E. Gallino G.	2008	-	98	

Epidemiological study of the risk of colorectal cancer in association to long-term exposure to water disinfection products

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/27	Buzzoni R.	2008	II	18	8

Perioperative treatment with CO-E (capecitabine, oxaliplatin, irinotecan and cetuximab) of liver metastasis of colorectal carcinoma potentially resectable although at high risk of recurrences

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/29	Bajetta E.	2008	II	17	3

First line UFT,Oxaliplatin and Erbitux combination (TEFAFOX-E) in elderly (≥ 70 years) metastatic colorectal patients: a phase II I.T.M.O. study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/38	Mazzaferro V.	2008	III	46	12

A phase III randomized, double-blind, placebo-controlled study of sorafenib as adjuvant treatment for hepatocellular carcinoma after surgical resection or local ablation (STORM)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/56	Casali P.	2008	II	10	3

An open-label, multicenter, single-arm study to evaluate the efficacy of nilotinib in adult patients with metastatic or unresectable gastrointestinal stromal tumors in first line treatment

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/61	Casali P.	2008	III	11	Closed accrual

An open label, multicenter, expanded access study of imatinib mesylate in adult patients with GIST in adjuvant setting after RO-resection

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/71	Bajetta E.	2008	II	22	3

Efficacy and safety of RAD001 (Everolimus) in patients affected by biliary tract cancer progressing after prior chemotherapy: a phase II I.T.M.O. study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/01	Bajetta E.	2009	III	1	0

Open label extension study of lanreotide autogel 120 mg in patients with non functioning entero-pancreatic endocrine tumour

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/12	Bajetta E.	2009	II	30	15

Capecetabine in combination with oxaliplatin, irinotecan and bevacizumab (CO-B regime) as first.line therapy for metastatic colorectal cancer: a phase II ITMO study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/15	Mazzaferro V.	2009	II	3	

A phase II randomized, double-blind, placebo-controlled study of sorafenib or placebo in combination with transarterial chemoembolization (TACE) performed with DC bead and doxorubicin for intermediate stage hepatocellular carcinoma (HCC)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/24	Mazzaferro V.	2009	III	6	2

A randomized, double-blind, multicenter phase III study of brivanib plus best supportive care (BSC) versus placebo plus BSC in subjects with advanced hepatocellular carcinoma (HCC) who have failed or are intolerant to sorafenib

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/30	Mazzaferro V.	2007(31/12/10)	II	52	Closed accrual

Radioembolization with Yttrium-90 glass microspheres for intermediate or advanced hepatocellular carcinoma not eligible to curative approach: a phase II study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/31	Casali P.	2009	III	9	7

An open-label, multicenter study to evaluate the efficacy of nilotinib in adult patients with gastrointestinal stromal tumors resistant to imatinib and sunitinib

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/37	Mazzaferro V.	2009	Observational	28	14

Development of programs for weak subjects within the transplant system: optimal use of organs

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/61	Mazzaferro V.	2010	II	2	2

An uncontrolled open label multicenter phase II safety study of BAY73-4506 in patients with hepatocellular carcinoma (HCC)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/79	Casali P.	2010	Observational	51	51

Observational study of plasma levels of Imatinib in patients with gastrointestinal stromal tumor

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/80	Mazzaferro V.	2009	III	3	2

Controlled extension of conventional criteria for liver transplantation in hepatocellular carcinoma (HCC): a prospective validation study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
10/47	Mazzaferro V.	2010 (31/12/10)	Observational	320	320

Genomic predictors and oncogenic drivers in hepatocellular carcinoma

Genital apparatus

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/05	Raspagliesi F.	2005	II	79	3

Sentinel node detection in endometrial cancer: a multicenter study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/29	Villa S.	2005	I-II	31	Closed accrual

Irradiation of the prostate sheath and pelvic lymph nodes with intensity modulated photon beams in patients with clinically localized cancer of the prostate: phase III study

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
06/34	Bajetta E.	2006	II	5	Closed accrual

A randomized multicenter phase II trial of Patupilone (EPO906) plus Prednisone versus Docetaxel (Taxotere) plus Prednisone in patients with metastatic hormone refractory prostate cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/78	Daidone M.G., Salvioni R.	2006	Observational	150	3

Analysis of serum protein profiles for the early diagnosis of prostate cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/46	Valdagni R.	2007	-	142	49

Prostate cancer research international: active surveillance (PRIAS)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/54	Nicolai N.	2008	-	7	2

Identification of men with a genetic predisposition to prostate cancer: target screening in BRCA1/2 mutation carriers and controls - the IMPACTstudy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/67	Raspagliesi F.	2008	III	18	

A randomized, double-blind, placebo controlled, multicentre trial of abagovomab maintenance therapy in patients with epithelial ovarian cancer after complete response to first line chemotherapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/72	Procopio G.	2008	III	4	Closed accrual

A phase III, randomized, double-blind study to assess the efficacy and safety of 10 mg ZD4054 versus placebo in patients with hormone-resistant prostate cancer and bone metastasis who are pain free or mildly symptomatic

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/10	Bajetta E.	2008	Pilot	37	

Medical treatment with Ketoconazole of the advanced adenocarcinoma of the prostate. A pilot study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/30	Buzzoni R.	2008	III	2	2

A phase III, randomized, placebo-controlled, double-blind study to assess the efficacy and safety of once-daily orally administered ZD4054 10 mg in non-metastatic hormone-resistant prostate cancer patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/43	Raspagliesi F. Cerrotta A.	2008	III	1	1

Randomized phase III trial comparing concurrent chemoradiation and adjuvant chemotherapy with pelvic radiation alone in high risk and advanced stage endometrial carcinoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/54	Zanaboni F. Raspagliesi F.	2008	II	35	12

A prospective phase II multicentric study of weekly topotecan and cisplatin (topocis) as neoadjuvant treatment in patients with locally advanced squamous cervical cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/10	Raspagliesi F.	2009	III	14	12

Carboplatin and Paclitaxel administered every three weeks vs Carboplatin and Paclitaxel administered weekly to patients with ovary carcinoma: multicentric randomized study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/11	Raspagliesi F.	2009	-	13	0

TOTEM: controlled, randomized, multicenter clinical study investigating 2 follow-up regimens with different intensity in patients treated for endometrial carcinoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/17	Raspagliesi F.	2009	I	1	1

Phase I study on the intraperitoneal administration of ONCO-FID-P in patients with peritoneal carcinosis from an ovarian, gastric, breast, bladder or colon tumor

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/38	Raspagliesi F.	2009	II	5	5

A phase II, double-blind, placebo-controlled, multi-centre, randomized study of ZD4054 plus carboplatin and paclitaxel or placebo plus carboplatin and paclitaxel in patients with advanced ovarian cancer sensitive to platinum-based chemotherapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/65	Raspagliesi F.	2010	-	11	11

LION - Lymphadenectomy in ovarian neoplasm. An open-randomized, prospective, multicenter trial. A project of the AGO Study Group

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/71	Raspagliesi F.	2010	III	2	2

A phase III study to evaluate the efficacy and safety of pazopanib monotherapy versus placebo in women who have not progressed after first line chemotherapy for epithelial ovarian, fallopian tube, or primary peritoneal cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
10/38	Salvioni R.	2010	II	9	9

Tandem transplantation of autologous hematopoietic progenitors in relapsed/refractory patients with metastatic germinal tumors

Head & Neck and Thyroid Cancers

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/42	Licitra L.	2007	II	30	Closed accrual

SAMITAL in the prevention and care of mucositis induced by chemoradiation therapy in the treatment of cervico-facial neoplasias

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/05	Licitra L.	2008	II	5	Closed accrual

A phase II, randomized trial of chemoradiation with or without Panitumumab in subjects with unresected, locally advanced squamous cell carcinoma of the head and neck

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/46	Licitra L.	2008	II	9	1

An open label single arm trial investigating zalutumumab, a human monoclonal anti-EGF receptor antibody, in combination with best supportive care, in patients with non-curable squamous cell carcinoma of the head and neck who have failed standard platinum-based chemotherapy

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/04	Licitra L.	2009	II	13	2

Phase II, multicenter, open-label, single arm trial to evaluate the safety and efficacy of oral E7080 in medullary and iodine-131 refractory, unresectable differentiated thyroid cancers, stratified by histology

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/05	Licitra L.	2009	III	8	5

An international, randomized, double-blinded, phase III efficacy study of XL184 versus placebo in subjects with unresectable, locally advanced, or metastatic medullary thyroid cancer

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/52	Licitra L.	2009	I-II	6	2

Open-label, randomized, controlled phase I/II study of cilengitide to evaluate the safety and efficacy of the combination of different regimens of cilengitide added to cisplatin, 5-FU, and cetuximab in subjects with recurrent/metastatic squamous cell cancer of the head and neck (ADVANTAGE)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
10/02	Licitra L.	2010	II	7	7

Phase II study of Pemetrexed in combination with cisplatin and cetuximab in recurrent or metastatic squamous cell carcinoma of the head and neck

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
10/29	Locati L.	2010	II	12	12

Sorafenib in recurrent and/or metastatic salivary gland carcinomas

Hematologic Malignancies

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
04/14	Corradini P.	2004	I-II	6	Closed accrual

Rituximab maintenance treatment versus no further after a brief induction therapy with FDN + rituximab in elderly patients with advanced stage previously untreated follicular lymphoma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
04/32	Gianni A.M., Di Nicola M.	2004	Observational	20	

Prospective observational study in the adult with Burkitt's lymphoma of a polychemotherapy scheme in use in pediatrics

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/02	Corradini P.	2005	I-II	4	Closed accrual

A multicenter, open-label study of oral melphalan, and CC-5013 (Revlimid) (MPR) as induction therapy in elderly newly diagnosed multiple myeloma patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
05/34	Gianni A.M., Corradini P.	2005	III	36	6

Multicentric randomized phase III study that compares high-dose chemotherapy with rituximab and autotransplantation of circulating hemopoietic precursors with CHOP with rituximab administered every 14 days as first-line therapy for patients at high risk with large B-cell non-Hodgkin's lymphoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
05/64	Corradini P.	2006	III	10	Closed accrual

Randomized comparison of conditioning regimens of reduced intensity containing respectively anti-lymphocyte globulin versus alemtuzumab in allogeneic transplantation from non-family donors: global study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/12	Corradini P.	2006	II	12	Closed accrual

A phase II, multicenter study of bortezomib, pegylated liposomal doxorubicin, dexamethasone (PAD) as induction and melphalan (MEL 100) as transplant, in elderly newly diagnosed multiple myeloma patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/13	Corradini P.	2006	III	9	Closed accrual

A phase III, multicenter, randomized open-label study of velcade, melphalan, prednisone and thalidomide (V-MPT) versus velcade, melphalan, prednisone (V-MP) in elderly untreated multiple myeloma patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/14	Corradini P.	2006	III	13	Closed accrual

A phase III, prospective, randomized clinical study with velcade-thalidomide-dexamethasone versus thalidomide-dexamethasone for previously untreated patients with symptomatic multiple myeloma who are candidates to receive double autologous transplantation

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/28	Corradini P.	2006	III	4	Closed accrual

Zevalin at myeloablative doses in aggressive lymphomas of elderly patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/44	Corradini P.	2006	II	15	3

Intensive chemo-immunotherapy as first-line in adult patients with peripheral T-cell lymphoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/45	Corradini P.	2007	III	5	Closed accrual

A phase IIIb study of MabThera (rituximab) maintenance therapy in patients with follicular Non-Hodgkin's Lymphoma who have responded to induction therapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/50	Corradini P.	2006	II	12	Closed accrual

A phase II, multicenter study of Melphalan 100 mg/m² (MEL 100) as transplant, Revlimid and Prednisone (RP) as consolidation and Revlimid alone as maintenance in elderly newly diagnosed multiple myeloma patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/55	Corradini P.	2007	II	12	4

Bortezomib and dexamethasone treatment before donor lymphocyte infusions for myeloma patients progressing or relapsing after allogeneic transplantation of hematopoietic cells (FM-MYEL-06-01)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/67	Corradini P.	2007	II	3	Closed accrual

A phase II, multi-center, randomized, open label study of Velcade, Doxorubicin and Dexamethasone (PAD) vs Thalidomide and Dexamethasone (TD) in advanced and refractory multiple myeloma patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/38	Corradini P.	2007	III	6	1

A multicentric randomized trial in adult patients with acute myelogenous leukemia (AML) to compare: 1) a standard-dose versus high-dose remission induction regimen, and 2) an autologous blood stem cell transplantation versus an autologous blood cell-supported multicycle high-dose chemotherapy program,, within a risk-oriented postremission strategy reserving allogeneic stem cell transplantation for high-risk cases

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/48	Corradini P.	2007	II	10	7

Reduced intensity conditioning with high-dose rituximab followed by allogeneic transplantation of hematopoietic cells for the treatment of relapsed/refractory B-cell non Hodgkin's lymphomas

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/55	Corradini P.	2008	II	8	Closed accrual

Treatment with imatinib mesylate (Glivec) of severe chronic scleroderma-like GVHD, refractory to conventional immunosuppressive therapy

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/63	Corradini P.	2008	Observational	7	0

Lombardy registry of HCV positive lymphomas

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/76	Gianni A.M.	2008	II	30	4

Phase II study of Sorafenib for refractory/relapsed malignant lymphomas

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/02	Gianni A.M. Corradini P.	2008	III	7	Closed accrual

A phase III, multicentre, randomized, controlled study to determine the efficacy and safety of lenalidomide, melphalan and prednisone (MPR) versus melphalan (200 mg/m²) followed by stem cell transplant in newly diagnosed multiple myeloma subjects

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/14	Corradini P.	2008		-	48

A study of the protein profile expression with mass spectrometry (SELDI-TOF) for the identification of prognostic markers in the plasma of patients with chronic lymphatic leukemia

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/24	Corradini P.	2008	I-II	6	1

A phase Ia/II, multi-center, open-label study of HCD122 administered intravenously once weekly for four weeks in adult patients with advanced non-hodgkin's or Hodgkin's lymphoma who have progressed after least two prior therapies

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/33	Gianni A.M.	2008	II	33	12

Phase II study of perifosine in combination with sorafenib for refractory/relapsed malignant lymphomas

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/34	Corradini P.	2008	III	2	1

A randomized comparison between conditioning regimens to allogeneic transplant of hemopoietic stem cells containing I.V. Busulfan (I.V. Bu; Busilvex) with Fludarabine (BUFLU) versus I.V. Busulfan with Cyclophosphamide (BUCY2) in 40-55 years patients with acute myeloid leukemia (AML) in complete remission

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/44	Corradini P.	2008	-	50	1

Comparison of whole body diffusion weighted magnetic resonance imaging (DW-MRI) with skeletal X-ray and MRI of the spine for the assessment of bone disease in multiple myeloma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
08/49	Gianni A.M. Corradini P.	2008	II	15	4

Multicentre clinical study with early treatment intensification in patients with high-risk Hodgkin lymphoma, identified as FDG-PET scan positive after two conventional BVD courses

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/09	Gianni A.M. Corradini P.	2009	III	7	3

Phase III study comparing rituximab-supplemented ABVD (R-ABVD) with ABVD followed by involved-field radiotherapy (ABVD-RT) in limited-stage (stage I-IIA with no areas of bulk) Hodgkin's lymphoma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/13	Corradini P.	2009	II	1	0

Safety and efficacy of lenalidomide as main therapy in patients with newly diagnosed multiple myeloma following a tandem autologous-allogeneic transplant

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/23	Corradini P.	2009	Observational	15	7

A non-interventional observational post authorization safety study of subjects treated with lenalidomide

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
09/39	Corradini P.	2009	III	13	10

Phase III intergroup multicentre, randomized, controlled 3 arm parallel group study to determine the efficacy and safety of lenalidomide in combination with dexamethasone (Rd9 versus melphalan, prednisone and lenalidomide (MPR) versus cyclophosphamide, prednisone and lenalidomide (CPR) in newly diagnosed multiple myeloma subjects

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/46	Corradini P.	2009	III	15	10

A phase III, multicentre, randomized, controlled study to determine the efficacy and safety of cyclophosphamide, lenalidomide and dexamethasone (CRD) versus melphalan (200 mg/m²) followed by stem cell transplant in newly diagnosed multiple myeloma subjects

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/59	Gianni A.M.	2009	I-II	9	9

Phase I/II of dexamethasone, ofatumumab and bendamustine (TREANDA) (DOT) as first-line treatment of mantle cell lymphoma (MCL) in the elderly

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/69	Corradini P.	2010	III	9	9

A multicenter, randomized, double-blind, placebo controlled phase III study of panobinostat in combination with bortezomib and dexamethasone in patients with relapsed multiple myeloma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/76	Corradini P.	2010	II	2	2

Brief induction chemoimmunotherapy with rituximab + bendamustine + mitoxantrone followed by rituximab in elderly patients with advanced stage previously untreated follicular lymphoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/07	Corradini P.	2010	-	2	2

Monitoring of human polyomavirus reactivation in patients with lymphoproliferative disease treated with chemotherapy, chemotherapy and rituximab, and rituximab

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/12	Corradini P.	2010	I-II	2	2

A phase I/II, multicenter, open label study of pomalidomide cyclophosphamide and prednisone (PCP) in patients with multiple myeloma relapsed and/or refractory to lenalidomide

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/13	Corradini P.	2010	Observational	8	8

Prospective audit on stem cell mobilization in malignant lymphoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/31	Gianni A.M.	2010	III	1	1

A randomized, double-blind, placebo-controlled phase III study of SGN-35 (brentuximab vedotin) and best supportive care (BSC) versus placebo and BSC in the treatment of patients at high risk of residual Hodgkin lymphoma (HL) following autologous stem cell transplant (ASCT)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/49	Magni M.	2010	Observational	70	70

Outcome of second-line treatment in patients with relapsed follicular lymphoma according to the type of first-line treatment received

Lung Cancers

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
05/53	Pastorino U.	2006	-	4097	210

Spiral CAT, biomarkers and proteomic analysis, associated to a program of primary prevention for the early diagnosis of lung cancer: randomized study in subjects at high risk: project MILD

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/18	Platania M.	2007	III	5	1

START - Stimulating Targeted Antigenic Responses To NSCLC

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/22	Bajetta E.	2007	II	8	Closed accrual

Randomized phase II study of pemetrexed versus pemetrexed and carboplatin as second line chemotherapy in advanced non-small cell lung cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/35	Bajetta E.	2007	II	4	Closed accrual

A phase II study of NGR-hTNF administered as single agent every 3 weeks in patients affected by advanced or metastatic malignant pleural mesothelioma previously treated with no more than one systemic therapeutic regimen

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/28	Bajetta E.	2008	II	5	Closed accrual

Phase II study of the combination of bevacizumab plus pemetrexed and carboplatin as first line therapy in patients with malignant pleural mesothelioma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/40	Bajetta E.	2008	II	17	5

A phase II, randomized, double blind, two arm, parallel study of vandetanib (ZACTIMA, ZA6474) plus gemcitabine (Gemzar) versus gemcitabine plus placebo as first line treatment of advanced 8stage IIIb or IV) non small cell lung cancer (NSCLC) elderly patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/63	Zilembo N.	2008	II	2	Closed accrual

A randomized phase II study of ixabepilone plus carboplatin and paclitaxel plus carboplatin in subjects with advanced non small cell lung cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/64	Bajetta E.	2008	III	9	4

A phase III, randomized, double-blind, placebo-controlled multi-center study of ASA404 in combination with docetaxel in second-line treatment of patients with advanced or metastatic (stage IIIb/IV) non-small cell lung cancer (NSCLC)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/27	Zilembo N.	2009	II	25	13

A randomized phase II study with NGR-hTNF in combination with standard chemotherapy regimen vs standard chemotherapy regimen in non-pretreated patients with advanced non-small cell lung cancer (NSCLC)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/74	Buzzoni R.	2010	III	8	8

A randomized, multicenter, open-label phase III study of gemcitabine-cisplatin chemotherapy plus IMC-11F8 versus gemcitabine-cisplatin chemotherapy alone in the first-line treatment of patients with squamous stage IIIb or IV non-small cell lung cancer (NSCLC)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/75	Buzzoni R.	2010	III	1	1

A randomized, multicenter, open-label phase III study of pemetrexed-cisplatin chemotherapy plus IMC-11F8 versus pemetrexed-cisplatin chemotherapy alone in the first-line treatment of patients with nonsquamous stage IIIb or IV non-small cell lung cancer (NSCLC)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/03	Platania M.	2010	III	4	4

A phase III, randomized, double-blind, placebo controlled study of oral talactoferrin in addition to best supportive care in patients with non-small cell lung cancer who have failed two or more prior treatment regimens

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/09	Pastorino U.	2010	Observational	20	20

Observational feasibility study of autologous adipose tissue derived mesenchymal stem cell transplantation, after laser resection of lung, in 20 metastasectomies

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/10	Bajetta E.	2010	III	1	1

Randomized proteomic stratified phase III study of second line erlotinib versus chemotherapy in patients with inoperable non-small cell lung cancer- PROSE Study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/41	Pastorino U.	2010	I-II	22	22

A prospective randomized phase I/II study on anatomic lung resections using laser, without mechanical suturing devices for parenchyma and synthetic materials for aerostasis versus standard treatment

Melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
01/36	Santinami M., Cascinelli N.	2002	III	112	Closed accrual

Peg intron versus observation after regional node dissection in AJCC stage III (TxN1/2M0) melanoma patients: a randomized trial

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
03/25	Rivoltini L.	2003	I-II	21	Closed accrual

A phase III study of active vaccination with autologous T-lymphocytes trasduced with HSV-TK and MAGE-A3 in patients with metastatic melanoma and expression of MAGE-A3

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/06	Bajetta E.	2006(29/04/10)	II	10	Closed accrual

A phase II, open-label, single arm study to evaluate the efficacy, safety, tolerability and pharmacokinetics of ticilimumab in patients with advanced refractory and/or relapsed melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/43	Bajetta E.	2007 (16/03/10)	II	16	Closed accrual

Italian Multicenter Phase II Trial using Fotemustine plus Bevacizumab As First-Line Therapy in Metastatic Melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/11	Bajetta E.	2008	I	9	2

A dose-finding study with fotemustine fixed dose in combination with docetaxel in pretreated with metastatic melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/52	Santinami M.	2009	III	21	11

A double-blind, randomized, placebo-controlled phase III study to assess the efficacy of recMAGE-A3 + AS15 ASCI as adjuvant therapy in patients with MAGE-A3 positive resected stage III melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/55	Bajetta E.	2008	III	8	Closed accrual

A multicenter, randomized, double-blind study of dacarbazine with or without Genasense in chemotherapy naive subjects with advanced melanoma and low LDH (the AGENDA trial)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/73	Santinami M.	2009	I	8	1

Phase I dose-finding study of tumor-targeting human monoclonal antibody-cytokine fusion protein L19TNFalfa plus melphalan using isolated inferior limb perfusion in patients with in-transit stage III/IV melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/42	Del Vecchio M.	2009	III	1	1

An open label, multicenter, phase III trial of ABI-007 vs dacarbazine in previously untreated patients with metastatic malignant melanoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/06	Del Vecchio M.	2010	III	10	10

BRIM 3: a randomized, open-label, controlled, multicenter, phase III study in previously untreated patients with unresectable stage IIIC or stageIV melanoma with V600E BRAF mutation receiving RO5185426 or dacarbazine

Sarcomas

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
01/46	Gronchi A.	2001	III	96	Closed accrual

Localized high-risk soft-tissue sarcomas of the extremities and superficial trunk in adults: an integrated approach comprising 3 or 5 cycles of adjuvant chemotherapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
03/31	Casali P.	2003	II-III	10	0

EUROpean Bone Over 40 Sarcoma Study. An european treatment protocol for bone-sarcoma in patients older than 40 years

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
03/45	Gronchi A.	2003	Pilot	39	4

Pre-operative chemo-radiation therapy in retroperitoneal soft tissue sarcomas (\pm RT boost)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
03/46	Bertulli R.	2004	II	21	Closed accrual

Ifosfamide at high doses in prolonged continuous infusion by a portable infusion system in soft-tissue sarcomas typical of the adult in an advanced phase in second/further line chemotherapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
04/01	Bertulli R.	2004	II	15	Closed accrual

Gemcitabine in leiomyosarcoma in an advanced phase in second or further line of chemotherapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
04/20	Corradini P.	2004	II	2	

Transplant of hemopoietic stem cells from family HLA-identical donor after conditioning at reduced intensity in soft tissue sarcoma in a metastatic phase

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
04/33	Casali P.	2004	II	16	Closed accrual
Phase II study of imatinib mesylate in chordoma					
05/31	Ferrari A.	2005	III	62	20
A protocol for localized non-rhabdomyosarcoma soft tissue sarcoma					
05/32	Ferrari A.	2005	III	93	30
EpSSG NRSTS 2005. A protocol for localized non-rhabdomyosarcoma soft tissue sarcoma					
06/53	Casali P.	2006	II	23	1
Trabectedin (ET743) in metastatic or locally advanced cell liposarcoma pretreated with chemotherapy					
07/11	Stacchiotti S.	2007	II	10	Closed accrual
Open-label trial of imatinib in patients with desmoid tumor and chondrosarcoma					
07/39	Casali P.	2007	II	11	
Phase II, non randomized, open-label, single arm trial of patients with advanced or metastatic osteosarcomas, administered with pemetrexed (Alimta, 500 mg/m ² by intravenous infusion of 10 minutes)					
08/01	Casali P.	2008	Pilot	1	Closed accrual
A pivotal trial to determine the efficacy and safety of AP23573 when administered as maintenance therapy to patients with metastatic soft-tissue or bone sarcoma					
08/04	Casali P., Casanova M.	2008	I-II	11	
A phase I/phase II study of CP-751,871 in patients with relapsed and/or refractory Ewing's sarcoma family of tumors Casali P.					
08/22	Casali P.	2008	II	3	Closed accrual
Phase II, non-randomized study of second line treatment with sarafenib (BAY 43-9006) in patients affected by relapsed high-grade osteosarcoma					
08/25	Casali P.	2008	III	2	1
A multinational, randomized, double-blind placebo controlled study of AVE8062 (25 mg/m ²) administered every 3 weeks, in patients with advanced - stage soft tissue sarcoma treated with cisplatin (75 mg/m ²) after failure of anthracycline and ifosfamide chemotherapies					
08/26	Casali P.	2008	II	11	
Multicenter, single-arm, single-stage, phase II trial to determine the preliminary efficacy and safety of RAD001 in patients with histological evidence of progressive or metastatic bone or soft tissue sarcomas					
08/45	Casali P.	2008	III	1	
A randomized, multicenter, phase III trial of Trabectedin (yondelis) versus doxorubicin-based chemotherapy as first-line therapy in patients with traslocation related sarcomas (TRS)					
08/57	Casali P.	2008	III	11	Closed accrual
A randomized double-blind phase III trial of pazopanib versus placebo in patients with soft tissue sarcoma whose disease has progressed during or following prior therapy					
08/62	Casali P.	2008	II	14	4
Open label, multi-center, phase II study denosumab in subject with giant cell tumor of bone					
09/58	Casali P.	2009	II	9	6
Phase II study of lapatinib in EGRF/HER2NEU positive advanced chordoma					

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/78	Casali P. Raspagliesi F.	2010	II	2	2

A phase II randomized - non comparative - study on the activity of trabectedin or gemcitabine + docetaxel in metastatic or locally relapsed uterine leiomyosarcoma pretreated with conventional chemotherapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/30	Casali P.	2010	II	4	4

Randomized phase II study evaluating two doses of NGR-hTNF administered either as single agent or in combination with doxorubicin in patients with advanced soft tissue sarcoma (STS)

Urinary apparatus

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/38	Bajetta E.	2006	II	56	Closed accrual

A randomized open-label multicenter phase II study of first line therapy with Sorafenib in association with IL-2 versus Sorafenib alone in patients with unresectable and/or metastatic renal cell cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/62	Buzzoni R.	2007	III	8	Closed accrual

A randomized, double-blind, placebo-controlled, multicenter phase III study to compare the safety and efficacy of RAD001 plus best supportive care (BSC) versus BSC plus placebo in patients with metastatic carcinoma of the kidney which has progressed on VEGF receptor tyrosine kinase inhibitor therapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/53	Procopio G.	2007	III	5	3

Sunitinib treatment of renal adjuvant cancer (S-TRAC): a randomized double-blind phase III study of adjuvant sunitinib vs placebo in subjects with high risk RCC

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/41	Procopio G.	2008	II	7	1

A randomized, open label, multi-center phase II study to compare bevacizumab plus RAD001 versus interferon alfa-A plus bevacizumab for the first-line treatment of patients with metastatic clear cell carcinoma of the kidney

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/51	Procopio G.	2008	III	5	Closed accrual

Axitinib (AG 013736) as second line therapy for metastatic renal cell cancer: AXIS trial

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/70	Salvioni R.	2009	II	31	30

Phase II study with the multi-target tyrosine-kinase inhibitor Pazopanib (GW786034) for patients with relapsed or refractory urothelial cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/11	Procopio G.	2010	II	2	2

Phase II study of sunitinib in metastatic renal cancer with non-clear cell histology

Pediatric tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
95/26	Cefalo G. Luksch R.	1995	II	83	5

Immunotherapy (IL-2 and activated circulating mononucleate cells) and pre- and post-surgical antineoplastic chemotherapy in the primary treatment of osteosarcoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
01/33	Luksch R.	2001	II	31	Closed accrual

Prospective randomized study for the treatment of nonmetastatic osteosarcoma of the extremities

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
01/40	Luksch R.	2002	III	44	5

Protocol NB-AR-01: First European Cooperative Study for high-risk neuroblastoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
01/41	Seregini E., Bombardieri E.	2001	Observational	277	17

Protocol for evaluation and therapy of the diencephalohypophysial alterations in pediatric patients with cerebral neoplasms

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
03/12	Massimino M.	2003	Observational	36	

Second protocol for diagnosis and treatment of ependymoma in a pediatric age

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
03/13	Luksch R.	2003	II	17	2

Non-controlled clinical study for the treatment of Ewing's sarcoma in relapse

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
03/14	Spreafico F.	2003	Observational	81	9

Wilms' tumor: diagnostic-therapeutic protocol AIEOP 2003

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
03/16	Terenziani M.	2003	III	276	40

Germ cell tumors: diagnostic-therapeutic protocol AIEOP 2003

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
04/21	Gandola L.	2004	III	14	Closed accrual

(HIT-SIOP PNET 4. A SIOP and GPOH TRIAL). A prospective randomized controlled trial of hyperfractionated versus conventionally fractionated radiotherapy in standard-risk medulloblastoma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/17	Luksch R. Castellani M.R.	2005	II	1	0

Phase II protocol with combined chemotherapy and 131I-MIBG in the treatment of patients with neuroblastoma resistant or in relapse (I-METCH)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/26	Luksch R.	2006	Pilot	5	1

Ewing's family tumors at high risk: pilot study comprising a window-therapy with cisplatin, intensive chemotherapy, RT, consolidation with non-myeloablative immunosuppressive chemotherapy and allotransplant of hemopoietic cells

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
05/60	Ferrari A.	2005	II	2	Closed accrual

Open study with Glivec (imatinib mesylate) in the treatment of patients affected by refractory desmoplastic small round cell tumor, that expresses a molecular target of Glivec (PDGF-R α/β c-KIT)

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
06/23	Luksch R.	2006	II	7	1

Phase II study of Glivec (Imatinib Mesylate) in patients with advanced neuroblastoma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
06/30	Luksch R., Anichini A.	2006	Observational	148	4

Study of the immune response to tumor-associated antigen in pediatric patients with solid tumors for the development of innovative immunological therapies

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/05	Cefalo G.	2007(31/07/10)	II	16	3

A phase II study on the chemosensitizer efficacy and of proton pump inhibitors (PPI) in the primary chemotherapy of osteosarcoma

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/08	Cefalo G.	2007	III	13	2

LCH-III. Treatment protocol of the third international study for Langerhan's cell histiocytosis

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/17	Luksch R.	2008(06/06/10)	II	2	Closed accrual

A phase II study of safety and efficacy of a single dose of pegfilgrastim, 100 mcg/kg (max 6 mg) after mobilizing chemotherapy in the collection of peripheral autologous stem cells in oncologic pediatric patients

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/31	Luksch R.	2007	-	14	4

Guidelines for the treatment of patients with localized resectable neuroblastoma and analysis of prognostic factors

Study code	Coordinator	Activated (closed)	Phase	Total patients	Patients enrolled in 2010
07/36	Casanova M.	2007	II	5	Closed accrual

International randomized study to evaluate the addition of docetaxel to the combination of cisplatin-5-fluorouracil (TCF) vs. cisplatin-5-fluorouracil (CF) in the induction treatment of nasopharyngeal carcinoma (NPC) in children adolescent

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/13	Casanova M.	2008	II	4	0

Open-label, multi-center, randomized, two stage adaptive design study of the combination of bevacizumab with standard chemotherapy in minor patients with metastatic rhabdomyosarcoma, non-rhabdomyosarcoma soft-tissue sarcoma or Ewing sarcoma/soft tissue primitive neuroectodermal tumour

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/17	Cefalo G.	2008	II	10	4

HL PED 2008 Hodgkin's lymphoma. A therapeutic protocol for sequels reduction

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/22	Casali P. Luksch R.	2009	III	4	3

A phase II study on the efficacy of dose intensification in patients with non-metastatic Ewing's sarcoma

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/25	Casali P. Luksch R.	2009	II	2	2

Therapeutic protocol with high-dose chemotherapy, radiotherapy, maintenance therapy with low-dose Cyclophosphamide and anti-COX2 in metastatic Ewing's sarcoma: ISG/AIEOP study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/57	Casanova M.	2009	II	7	7

Phase II single-arm studies of temozolomide in combination with topotecan in refractory or relapsing neuroblastoma and other paediatric solid tumor

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/63	Massimino M.	2010	Observational	10	10

Brain tumor in children: an aid to parent child communication about the disease

Palliative care

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/01	Ripamonti C.	2007	I-II	34	Closed accrual

Treatment of the osteonecrosis of the mandible by medical gaseous ozone and in oily suspension. A phase III study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/69	Caraceni A.	2010	Observational	17	17

A multicentric data collection on terminal/palliative sedation therapy and its monitoring for refractory symptoms

Miscellanea

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
02/27	Terenziani M.	2002	Pilot	153	60

Program of control in patients subjected to radiotherapy comprising the breast region during infancy and adolescence

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
05/66	Tagliabue G. Contiero P.	2006	Observational	10738	536

Registry of congenital malformations in Lombardy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
06/77	Celio L.	2007	II	10	Closed accrual

Phase II study of PHA-739358 administered by a 24-Hour IV infusion every 14 days in advanced/metastatic breast, ovary, colorectal, pancreatic, small cell lung and non-small-cell lung cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/03	Buzzoni R.	2007	III	8	Closed accrual

A randomized, double-blind, placebo controlled, multicenter phase III study in patients with advanced carcinoid tumor receiving Sandostatin LAR and RAD001 or Sandostatin LAR and placebo

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/40	Gianni L.	2007	I	23	3

Dose-finding study of Caelix and RAD001 in patients with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
07/73	Bombardieri E.	2007	II	32	16

Evaluation of the efficacy of the associated treatment [90 Y-DOTA, Tyr(3)] Octreotate and [177Lu-DOTA, Tyr(3)] Octreotate in patients with neuroendocrine neoplasias expressing receptors for somatostatin, refractory to conventional biotherapy and/or chemotherapy treatments

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/12	Gianni L.	2008	Ib	57	31

An open-label, safety, pharmacokinetics and pharmacodynamic dose escalation phase Ib study of pazopanib in combination with epirubicin or doxorubicin in subjects with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/15	Bajetta E.	2008	III	13	0

Sorafenib long term extension program (STEP)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/19	Gianni L.	2008	I	9	

An open-label, non-randomized, dose escalation, safety and pharmacokinetics phase I study of AVE8062 in combination with cisplatin administered on day 1 followed by docetaxel on day 2, every 3 weeks, in patients with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/21	Buzzoni R.	2008	III	6	Closed accrual

MAGELLAN - Multicenter, randomized, parallel group efficacy superiority study in hospitalized medically ill patients comparing rivaroxaban with anoxaparin

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/32	Licitra L.	2008	II	6	Closed accrual

Randomized phase II feasibility study of Cetuximab combined with 4 cycles of TPF followed by platinum based chemo-radiation strategies

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/48	Borreani C.	2008	-	61	

Study of the psychological impact of prevention programmes in women who underwent BRCA1/BRCA2 genetic test

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/50	Favaro M.	III	2		

ALBumIn Italian Outcome Sepsis study- ALBIOS STUDY "Efficacy of albumin administration for volume replacement in patients with severe sepsis or septic shock"

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/69	Caraceni A.	2008	IV	2	2

A randomized, double-blind, placebo-controlled study of a fixed dose of subcutaneous methylaltrexone in adults with advanced illness and opioid-induced constipation: efficacy, safety, and additional health outcomes

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
08/70	Caraceni A.	2008	IV	1	1

Open extension study to evaluate the safety of a fixed subcutaneous dose of methylaltrexone in patients with advanced diseases and constipation from opioids Caraceni A.

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/06	Bajetta E.	2009	II	35	13

An open label, single arm, phase II study of combination RAD001 and octreotide LAR in patients with advanced neuroendocrine tumors as first line treatment

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/08	Tognoli E.	2009	II	60	60

Methadone for postoperative analgesia after balanced anaesthesia integrated with low dose ketamine S(+)

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/32	Decarli A.	2009	Observational	445	445

Epidemiologic studies on environmental risk factors and their interactions with genetic factors of bladder cancer and sarcomas

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/35	Pastorino U.	2009	-	374	371

Efficacy of thermal treatment for respiratory airways in heavy smokers

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/36	Gianni L.	2009	I-II	4	2

Dose-finding study of combination of trabectedin and cisplatin in patients with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/41	Licitra L.	2009	III	18	17

Role of aprepitant in prevention of late vomiting due to cisplatin: a controlled, double-blind study

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/47	Gianni L.	2009	I	8	5

A phase I. open label, multicenter, study to assess the safety. Tolerability and pharmacology of AZ D2281 in combination with liposomal doxorubicin (Caelyx) in patients with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/53	Gianni L.	2009	I	12	8

Phase I dose escalation study evaluating the safety and tolerability of PankomabGEX tm in patients with advanced, TA-MUC1 positive solid malignancies who are not longer eligible for standard therapy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/54	Gianni L.	2009	I	10	10

Phase Ib study of CC-5013 and paclitaxel in patients with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/55	Gianni L.	2009	I	15	15

Phase I dose finding and pharmacokinetic study of daily administrations of the intravenous camptothecin Namitecan (ST1968) in patients with refractory or recurrent solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/72	Corradini P.	2009	Observational	52	

Evaluation of the immune response after anti-flu vaccination against H1N1 pandemic virus in oncologic and hematologic patients

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
09/73	Ravagnani F.	2010(30/06/10)	-	12	12

Spectra Optia- 2nd generation MNC protocol: feasibility study for the collection of autologous stem cells

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/04	Nicolai N.	2010	-	31	31

A prospective evaluation of morbidity parameters and postoperative and medium-term quality of life of patients submitted to videolaparoscopic vs open retroperitoneal lymphadenectomy

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/20	Meroni E.	2010	Observational	1	1

Walflex Italian National Esophageal Registry

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/32	Gianni L.	2010	I	1	1

Dose-escalation, PK and safety study with single agent CetuGEX in patients with locally advanced and/or metastatic cancer

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/42	Gianni A.M.	2010	I	2	2

An open-label, non-randomized dose escalation, safety and pharmacokinetics phase I study of ombrabulin (AVE8062) in combination with bevacizumab administered by intravenous infusion every 3 weeks in patients with advanced solid tumors

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/55	Morosi C.	2010	-	1	1

Evaluation of the response according to dimensional and tissue criteria using contrast-enhanced amplifier ultrasonography in patients with soft tissue sarcomas or gastrointestinal stromal tumors (GIST) after molecular target therapies - CONTICANET

<i>Study code</i>	<i>Coordinator</i>	<i>Activated (closed)</i>	<i>Phase</i>	<i>Total patients</i>	<i>Patients enrolled in 2010</i>
10/68	Ripamonti C.	2010	Observational	55	55

Validation in Italian language of the questionnaire "patient dignity inventory" and evaluation of the relationship between perceived dignity and parameters of physical, emotional, spiritual and religious well-being in patients with solid and hematologic tumors in active oncological therapy