



Fondazione IRCCS
Istituto Nazionale dei Tumori

Sistema Socio Sanitario



Regione
Lombardia

APPENDIX SCIENTIFIC REPORT

2016-2017



SCIENTIFIC

REPORT

2016-2017

APPENDIX



APPENDIX

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ONGOING PROJECTS
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ORGANIZATIONS 2016-2017



PUBLICATIONS

2016

	AUTHORS	TITLE	JOURNAL	I.F.
1	AGNOLI C, GRIONI S, KROGH V, PALA V, Allione A, Matullo G, Di Gaetano C, TAGLIABUE G, PEDRAGLIO S, GARRONE G, CANCARINI I, CAVALLERI A, SIERI S.	Plasma riboflavin and vitamin B-6, but not homocysteine, folate, or vitamin B-12, are inversely associated with breast cancer risk in the european prospective investigation into cancer and nutrition-varese cohort.	Journal Of Nutrition 2016;146:1227-1234	3.74
2	AGRESTI R, MENEGHINI E, BAILI P, MINICOZZI P, TURCO A, CAVALLO I, FUNARO F, AMASH H, BERRINO F, TAGLIABUE E, SANT M.	Association of adiposity, dysmetabolisms, and inflammation with aggressive breast cancer subtypes: a cross-sectional study.	Breast Cancer Research And Treatment 2016;157:179-189	4.085
3	ALESSI A, MARTINELLI F, PADOVANO B, SERAFINI G, LORUSSO D, LORENZONI A, DITTO A, LECCE F, MIRA M, DONFRANCESCO C, RASPAGLIESI F, CRIPPA F.	FDG-PET/CT to predict optimal primary cytoreductive surgery in patients with advanced ovarian cancer: Preliminary results.	Tumori 2016;102:103-107	1.071
4	ALFIERI S, RIPAMONTI CI, Marceglia S, ORLANDI E, IACOVELLI NA, GRANATA R, CAVALLO A, POZZI P, BOFFI R, BERGAMINI C, IMBIMBO M, PALA L, RESTEGHINI C, MIRABILE A, LOCATI LD, LICITRA L, BOSSI P.	Temporal course and predictive factors of analgesic opioid requirement for chemoradiation-induced oral mucositis in oropharyngeal cancer	Head And Neck-journal For The Sciences And Specialties Of The Head And Neck 2016;38 Suppl 1:E1521-E1527	2.76
5	Allen NE, Travis RC, Appleby PN, Albanes D, Barnett MJ, Black A, Bueno De Mesquita HB, Deschamps M, Galan P, Goodman GE, Goodman PJ, Gunter MJ, Heliovaara M, Helzlsouer KJ, Henderson BE, Hercberg S, Knekt P, Kolonel LN, Lasheras C, Linseisen J, et al. [Pala V].	Selenium and Prostate Cancer: Analysis of Individual Participant Data From Fifteen Prospective Studies.	Jnci-journal Of The National Cancer Institute 2016;108:	11.37
6	Allione A, Di Gaetano C, Dani N, Barberio D, SIERI S, KROGH V, Matullo G.	Anticoagulants used in plasma collection affect adipokine multiplexed measurements.	Cytokine 2016;80:43-47	2.94
7	Alnagh S, Loo KJ, Cutajar DL, Jalayer M, TENCONI C, Favoino M, Rietti R, Tartaglia M, Carriero F, Safavi Naeini M, Bucci J, Jakubek J, Pospisil S, Zaider M, Lerch MLF, Rosenfeld AB, Petasecca M.	BrachyView: Multiple seed position reconstruction and comparison with CT post-implant dosimetry.	Journal Of Instrumentation 2016;11:	1.31
8	Alterio D, Franco P, Numico G, LICITRA L, Cossu Rocca M, Ferrari A, Pinto C, Russi EG, Ricardi U, Jereczek Fossa BA.	Non-surgical organ preservation strategies for locally advanced laryngeal tumors: what is the Italian attitude? Results of a national survey on behalf of AIRO and AIOM.	Medical Oncology 2016;33:76	2.486
9	Ambatipudi S, Cuenin C, Hernandez Vargas H, Ghantous A, Le Calvez Kelm F, Kaaks R, Barddahl M, Boeing H, Aleksandrova K, Trichopoulou A, Lagiou P, Naska A, Palli D, KROGH V, Polidoro S, Tumino R, Panico S, Bueno De Mesquita B, Peeters PH, Quirós JR, et al.	Tobacco smoking-associated genome-wide DNA methylation changes in the EPIC study.	Epigenomics 2016;8:599-618	4.044
10	Anantharaman D, Muller DC, Lagiou P, Ahrens W, Holcatova I, Merletti F, Kjaerheim K, Polesel J, Simonato L, Canova C, Castellsague X, Macfarlane TV, Znaor A, Thomson P, Robinson M, Conway DI, Healy CM, Tjonneland A, Westin U, Ekstrom J, et al. [Grioni S].	Combined effects of smoking and HPV16 in oropharyngeal cancer.	International Journal Of Epidemiology 2016;45:752-761	7.522



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	AUTHORS	TITLE	JOURNAL	I.F.
11	ANDRIANI F, BERTOLINI G, FACCHINETTI F, BALDOLI E, MORO M, CASALINI P, CASERINI R, MILIONE M, Leone G, PELOSI G, PASTORINO U, SOZZI G, ROZ L.	Conversion to stem-cell state in response to microenvironmental cues is regulated by balance between epithelial and mesenchymal features in lung cancer cells.	Molecular Oncology 2016;10:253-271	5.367
12	Angelini L, Bisogno G, Alaggio R, Scarzello G, Santoro L, Zanetti I, Scagnellato A, Basso E, D'Angelo P, FERRARI A, Castagnetti M.	Prognostic factors in children undergoing salvage surgery for bladder/prostate rhabdomyosarcoma.	Journal Of Pediatric Urology 2016;12:265.e1-265.e8	1.17
13	Annibalini G, Bielli P, De Santi M, Agostini D, Guescini M, Sisti D, Contarelli S, Brandi G, VILLARINI A, Stocchi V, Sette C, Barbieri E.	MIR retroposon exonization promotes evolutionary variability and generates species-specific expression of IGF-1 splice variants.	Biochimica Et Biophysica Acta-gene Regulatory Mechanisms 2016;1859:757-768	5.373
14	Antonia SJ, Lopez Martin JA, Bendell J, Ott PA, Taylor M, Eder JP, Jager D, Pietanza MC, Le DT, DE BRAUD F, Morse MA, Ascierto PA, Horn L, Amin A, Pillai RN, Evans J, Chau I, Bono P, Atmaca A, Sharma P, et al.	Nivolumab alone and nivolumab plus ipilimumab in recurrent small-cell lung cancer (CheckMate 032): a multicentre, open-label, phase 1/2 trial.	Lancet Oncology 2016;17:883-895	26.509
15	ARRIGHETTI N, COSSA G, DE CECCO L, STUCCHI S, CARENNINI N, CORNA E, GANDELLINI P, ZAFFARONI N, PEREGO P, GATTI L.	PKC-alpha modulation by miR-483-3p in platinum-resistant ovarian carcinoma cells.	Toxicology And Applied Pharmacology 2016;310:9-19	3.847
16	Ascierto PA, Agarwala S, Botti G, Cesano A, Ciliberto G, Davies MA, Demaria S, Dummer R, Eggermont AM, Ferrone S, Fu YX, Gajewski TF, Garbe C, HUBER V, Khleif S, Krauthammer M, Lo RS, Masucci G, Palmieri G, Postow M, et al.	Future perspectives in melanoma research: Meeting report from the "Melanoma Bridge". Napoli, December 1st-4th 2015.	Journal Of Translational Medicine 2016;14:313	3.694
17	Assi N, Moskal A, Slimani N, Viallon V, Chajes V, Freisling H, Monni S, Knueppel S, Forster J, Weiderpass E, Lujan Barroso L, Amiano P, Ardanaz E, Molina Montes E, Salmeron D, Quiros JR, Olsen A, Tjonneland A, Dahm CC, Overvad K, et al. [Agnoli C].	A treelet transform analysis to relate nutrient patterns to the risk of hormonal receptor-defined breast cancer in the European Prospective Investigation into Cancer and Nutrition (EPIC)	Public Health Nutrition 2016;19:242-254	2.433
18	Atlasi Y, Noori R, Marolin I, Franken P, Brandao J, Biermann K, COLLINI P, Grigorian M, Lukanidin E, Ambartsumian N, Fodde R.	The role of S100a4 (Mts1) in Apc- and Smad4-driven tumour onset and progression.	European Journal Of Cancer 2016;68:114-124	6.163
19	AVUZZI B, VALDAGNI R.	Bone metastases from prostate cancer: Radiotherapy.	Vaccines 2016;163-180	0
20	Azaro A, Rodón J, Machiels JP, Rottey S, DAMIAN S, Baird R, Garcia Corbacho J, Mathijssen RH, Clot PF, Wack C, Shen L, De Jonge MJ.	A phase I pharmacokinetic and safety study of cabazitaxel in adult cancer patients with normal and impaired renal function.	Cancer Chemotherapy And Pharmacology 2016;78:1185-1197	2.824
21	AZZOLLINI J, SCUVERA G, BRUNO E, PASANISI P, ZAFFARONI D, CALVELLO M, PASINI B, RIPAMONTI CB, COLOMBO M, Pensotti V, RADICE P, PEISSEL B, MANOUKIAN S.	Mutation detection rates associated with specific selection criteria for BRCA1/2 testing in 1854 high-risk families: A monocentric Italian study.	European Journal Of Internal Medicine 2016;32:65-71	2.591

PUBLICATIONS

2016

	AUTHORS	TITLE	JOURNAL	I.F.
22	BAGNOLI M, GRANATA A, NICOLETTI R, Krishnamachary B, Bhujwalla ZM, Canese R, Podo F, CANEVARI S, Iorio E, MEZZANZANICA D.	Choline metabolism alteration: A focus on ovarian cancer.	Frontiers In Oncology 2016;6:153	0
23	BAGNOLI M, CANEVARI S, Califano D, Losito S, Maio MD, RASPAGLIESI F, CARCANGIU ML, Toffoli G, Cecchin E, Sorio R, Canzonieri V, Russo D, Scognamiglio G, Chiappetta G, Baldassarre G, LORUSSO D, Scambia G, Zannoni GF, Savarese A, Carosi M, et al. [De Cecco L, Mezzanzanica D].	Development and validation of a microRNA-based signature (MiROvaR) to predict early relapse or progression of epithelial ovarian cancer: a cohort study.	Lancet Oncology 2016;17:1137-1146	26.509
24	BAGNOLI M, PIGNATA S, MEZZANZANICA D.	A miRNA signature assessing ovarian cancer prognosis.	Oncoscience 2016;3:308-310	0
25	BAILI P, DI SALVO F, De Lorenzo F, Maietta F, Pinto C, Rizzotto V, Vicentini M, Giorgi Rossi P, Tumino R, Rollo PC, TAGLIABUE G, CONTIERO P, Candela P, Scuderi T, Iannelli E, Cascinu S, Aurora F, AGRESTI R, TURCO A, SANT M, et al. [Meneghini E, Micheli A].	Out-of-pocket costs for cancer survivors between 5 and 10 years from diagnosis: an Italian population-based study.	Supportive Care In Cancer 2016;24:2225-2233	2.535
26	Bakker MF, Peeters PH, Klaasen VM, Bueno De Mesquita HB, Jansen EH, Ros MM, Travier N, Olsen A, Tjonneland A, Overvad K, Rinaldi S, Romieu I, Brennan P, Boutron Ruault MC, Perquier F, Cadeau C, Boeing H, Aleksandrova K, Kaaks R, Kuhn T, et al. [Krogh V].	Plasma carotenoids, Vitamin C, tocopherols, and retinol and the risk of breast cancer in the European Prospective Investigation into Cancer and Nutrition cohort.	American Journal Of Clinical Nutrition 2016;103:454-464	6.703
27	Baldi GG, Di Donato S, Fargnoli R, Dona M, BERTULLI R, Parisi E, Fantini L, Sbaraglia M, Panella M.	Complete response after rechallenge with trabectedin in a patient with previously responding high-grade undifferentiated sarcoma.	Anti-cancer Drugs 2016;27:908-913	2.268
28	Bandieri E, Romero M, RIPAMONTI CI, Artioli F, Fanizza C, Cascinu S, Bruera E, Luppi M.	Reply to O. Corli et al and M. Lucchesi et al.	Journal Of Clinical Oncology 2016;34:3580-3581	20.982
29	Bandieri E, Romero M, RIPAMONTI CI, Artioli F, Sichetti D, Fanizza C, Santini D, Cavanna L, Melotti B, Conte PF, Roila F, Cascinu S, Bruera E, Tognoni G, Luppi M.	Randomized trial of low-dose morphine versus weak opioids in moderate cancer pain.	Journal Of Clinical Oncology 2016;34:436-442	20.982
30	BARATTI D, KUSAMURA S, MILIONE M, PIETRANTONIO F, CAPORALE M, GUAGLIO M, DERACO M.	Pseudomyxoma Peritonei of Extra-Appendiceal Origin: A Comparative Study.	Annals Of Surgical Oncology 2016;23:4222-4230	3.655
31	BARATTI D, KUSAMURA S, DERACO M.	Colorectal cancer peritoneal metastases: Second-look laparotomy, prophylactic HIPEC, or both?	Annals Of Surgery 2016;263:e5	8.569
32	BARATTI D, KUSAMURA S, PIETRANTONIO F, GUAGLIO M, NIGER M, DERACO M.	Progress in treatments for colorectal cancer peritoneal metastases during the years 2010-2015. A systematic review.	Critical Reviews In Oncology Hematology 2016;100:209-222	5.039



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	AUTHORS	TITLE	JOURNAL	I.F.
33	BARONI S, Romero Cordoba S, PLANTAMURA I, DUGO M, D'IPPOLITO E, CATALDO A, Cosentino G, ANGELONI V, ROSSINI A, DAIDONE MG, IORIO MV.	Exosome-mediated delivery of miR-9 induces cancer-associated fibroblast-like properties in human breast fibroblasts.	Cell Death & Disease 2016;7:e2312	5.378
34	Barr RD, FERRARI A, Ries L, Whelan J, Bleyer WA.	Cancer in adolescents and young adults: A narrative review of the current status and a view of the future.	Jama Pediatrics 2016;170:495-501	9.528
35	Bartolo M, Chio A, Ferrari S, Tassorelli C, Tamburin S, Avenali M, Azicnuda E, Calvo A, CARACENI AT, Defazio G, De Icco R, Formisano R, Franzoni S, Greco E, Jedrychowska I, Magrinelli F, Manera U, Marchionni E, Mariotto S, Monaco S, et al.	Assessing and treating pain in movement disorders, amyotrophic lateral sclerosis, severe acquired brain injury, disorders of consciousness, dementia, oncology and neuroinfectiology. Evidence and recommendations from the Italian Consensus Conference on Pain in Neurorehabilitation.	European Journal Of Physical And Rehabilitation Medicine 2016;52:841-854	2.063
36	Bastholt L, Kreissl MC, Fuhrer D, Maia AL, LOCATI LD, Maciel L, Wu Y, Heller KN, Webster A, Elisei R.	Effect of an Outreach Programme on Vandetanib Safety in Medullary Thyroid Cancer.	European Thyroid Journal 2016;5:187-194	0
37	Bayer O, Câmara R, Zeissig SR, Ressing M, Dietz A, LOCATI LD, Ramroth H, Singer S.	Occupation and cancer of the larynx: a systematic review and meta-analysis.	European Archives Of Oto-rhino-laryngology 2016;273:9-20	1.627
38	BELLARDITA L, Damiano R, Porpiglia F, Scattoni V, Amodeo A, Bortolus R, Lapini A, Coccia A, Cicalese V, Caponera M, Mastrangelo P, Francesca F, VALDAGNI R, Taverna G, Di Trapani D, Leonardi R, Minocci D, Gaboardi F, Montanari E, Conti G.	Adaptation and validation of an Italian version of the Prostate Cancer Specific Quality of Life Instrument (PROSQOLI).	European Review For Medical And Pharmacological Sciences 2016;20:2773-2778	1.575
39	BELLI F, GRONCHI A, CORBELLINI C, MILIONE M, LEO E.	Abdominosacral resection for locally recurring rectal cancer.	World Journal Of Gastrointestinal Surgery 2016;8:770-778	0
40	Benjamin RS, CASALI PG.	Adjuvant imatinib for GI stromal tumors: When and for how long?	Journal Of Clinical Oncology 2016;34:215-218	20.982
41	BERETTA GL, DE CESARE M, ALBANO L, MAGNIFICO A, CARENNINI N, CORNA E, PEREGO P, GATTI L.	Targeting peptidyl-prolyl isomerase pin1 to inhibit tumor cell aggressiveness.	Tumori 2016;102:144-149	1.071
42	BERETTA GL, Cavalieri F.	Engineering nanomedicines to overcome multidrug resistance in cancer therapy.	Current Medicinal Chemistry 2016;23:3-22	3.455
43	BERETTA GL, ZAFFARONI N, Varchi G.	Novel 20(S)-sulfonylamidine derivatives of camptothecin and the use thereof as a potent antitumor agent: A patent evaluation of WO2015048365 (A1)	Expert Opinion On Therapeutic Patents 2016;26:637-642	4.626
44	BERGAMINI C, LOCATI L, BOSSI P, GRANATA R, ALFIERI S, RESTEGHINI C, IMBIMBO M, FALLAI C, ORLANDI E, TANA S, IACOVELLI NA, GUZZO M, IBBA T, COLOMBO S, BIANCHI R, PIZZI N, FONTANELLA W, LICITRA L.	Does a multidisciplinary team approach in a tertiary referral centre impact on the initial management of head and neck cancer?	Oral Oncology 2016;54:54-57	4.286

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	AUTHORS	TITLE	JOURNAL	I.F.
45	BERRINO F.	Impact of screening on breast cancer mortality-letter	Cancer Epidemiology Biomarkers & Prevention 2016;25:872	3.622
46	BERRINO F.	Mediterranean Diet and Its Association With Reduced Invasive Breast Cancer Risk	Jama Oncology 2016;2:535-536	0
47	Bertolini G, Nattino G, LANGER M, Tavola M, Crespi D, Mondini M, Rossi C, Previtali C, Marshall J, Poole D, Giviti.	The role of the intensive care unit in real-time surveillance of emerging pandemics: The Italian GiViTi experience	Epidemiology And Infection 2016;144:408-412	2.515
48	BIANCHI F, SOMMARIVA M, DE CECCO L, TRIULZI T, Romero Cordoba S, TAGLIABUE E, Sfondrini L, BALSARI A.	Expression and prognostic significance of the autoimmune regulator gene in breast cancer cells	Cell Cycle 2016;15:3220-3229	3.952
49	BOGANI G, CHIAPPA V, DITTO A, MARTINELLI F, DONFRANCESCO C, INDINI A, LORUSSO D, RASPAGLIESI F.	Morcellation of undiagnosed uterine sarcoma: A critical review	Critical Reviews In Oncology Hematology 2016;98:302-308	5.039
50	BOGANI G, DITTO A, MARTINELLI F, LORUSSO D, CHIAPPA V, DONFRANCESCO C, Di Donato V, INDINI A, Aletti G, RASPAGLIESI F.	Surgical Techniques for Diaphragmatic Resection during Cyto-reduction in Advanced or Recurrent Ovarian Carcinoma: A Systematic Review and Meta-analysis	International Journal Of Gynecological Cancer 2016;26:371-380	2.116
51	BOGANI G, FUCÀ G, MALTESE G, DITTO A, MARTINELLI F, SIGNORELLI M, CHIAPPA V, SCAFFA C, SABATUCCI I, LECCE F, RASPAGLIESI F, LORUSSO D.	Efficacy of adjuvant chemotherapy in early stage uterine leiomyosarcoma: A systematic review and meta-analysis	Gynecologic Oncology 2016;143:443-447	4.198
52	BOGANI G, DITTO A, MARTINELLI F, SIGNORELLI M, CHIAPPA V, LORUSSO D, SABATUCCI I, CARCANGIU ML, FIORE M, GRONCHI A, RASPAGLIESI F.	Morcellator's Port-site Metastasis of a Uterine Smooth Muscle Tumor of Uncertain Malignant Potential After Minimally Invasive Myomectomy	Journal Of Minimally Invasive Gynecology 2016;23:647-649	2.39
53	BOGANI G, DITTO A, MARTINELLI F, SIGNORELLI M, CHIAPPA V, SABATUCCI I, SCAFFA C, LORUSSO D, RASPAGLIESI F.	Extraperitoneal Robotic-Assisted Para-Aortic Lymphadenectomy in Gynecologic Cancer Staging: Current Evidence	Journal Of Minimally Invasive Gynecology 2016;23:489-496	2.39
54	BOGANI G, CHIAPPA V, DITTO A, MARTINELLI F, SIGNORELLI M, LORUSSO D, RASPAGLIESI F.	Morcellation of apparent benign uterine myoma: Assessing risk to benefit ratio	Journal Of Gynecologic Oncology 2016;27:e37	2.522
55	BOGANI G, MARTINELLI F, DITTO A, SIGNORELLI M, CHIAPPA V, RECALCATI D, LORUSSO D, RASPAGLIESI F.	Sentinel lymph node detection in endometrial cancer: Make injection site the difference?	Journal Of Gynecologic Oncology 2016;27:e23	2.522
56	Boikos SA, Xekouki P, FUMAGALLI E, Faucz FR, Raygada M, Szarek E, Ball E, Kim SY, Miettinen M, Helman LJ, Carney JA, Pacak K, Stratakis CA.	Carney triad can be (rarely) associated with germline succinate dehydrogenase defects	European Journal Of Human Genetics 2016;24:569-573	4.58
57	Bokhorst LP, Lepisto I, Kakehi Y, Bangma CH, Pickles T, VALDAGNI R, Alberts AR, Semjonow A, Strolin P, Montesino MF, Berge V, Roobol MJ, Rannikko A.	Complications after prostate biopsies in men on active surveillance and its effects on receiving further biopsies in the Prostate cancer Research International: Active Surveillance (PRIAS) study	Bju International 2016;118:366-371	4.387



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	AUTHORS	TITLE	JOURNAL	I.F.
58	Bokhorst LP, VALDAGNI R, Rannikko A, Kakehi Y, Pickles T, Bangma CH, Roobol MJ. Prias Study Group.	A Decade of Active Surveillance in the PRIAS Study: An Update and Evaluation of the Criteria Used to Recommend a Switch to Active Treatment	European Urology 2016;70:954-960	14.976
59	BOLLI N, Li Y, Sathiaseelan V, Raine K, Jones D, Ganly P, Cocito F, Bignell G, Chapman MA, Sperling AS, Anderson KC, Avet Loiseau H, Minvielle S, Campbell PJ, Munshi NC.	A DNA target-enrichment approach to detect mutations, copy number changes and immunoglobulin translocations in multiple myeloma	Blood Cancer Journal 2016;6:e467	4.411
60	Bonner MY, Karlsson I, RODOLFO M, Arnold RS, VERGANI E, Arbiser JL.	Honokiol bis-dichloroacetate (Honokiol DCA) demonstrates activity in vemurafenib-resistant melanoma <i>in vivo</i>	Oncotarget 2016;7:12857-12868	5.008
61	BONO A, TOLOMIO E, SANTINAMI M.	As easy as CC: A catchy, new mnemonic for the self-diagnosis of cutaneous melanoma	Giornale Italiano Di Dermatologia E Venereologia 2016;151:211-212	1.014
62	Bornhorst C, Tilling K, Russo P, Kourides Y, Michels N, Molnár D, Rodríguez G, Moreno LA, KROGH V, Ben Shlomo Y, Ahrens W, Pigeot I.	Associations between early body mass index trajectories and later metabolic risk factors in European children: the IDEFICS study	European Journal Of Epidemiology 2016;31:513-525	7.105
63	BOSSI P, ALFIERI S.	The Benefit of a Multidisciplinary Approach to the Patient Treated with (Chemo) Radiation for Head and Neck Cancer	Current Treatment Options In Oncology 2016;17:53	2.127
64	BOSSI P, Cortinovis D, Cossu Rocca M, Roila F, Seminara P, Fabi A, Canova S, Verri E, Fatigoni S, Iannace A, Macchi F, RIPAMONTI C.	Searching for evidence to support the use of ginger in the prevention of chemotherapy-induced nausea and vomiting	Journal Of Alternative And Complementary Medicine 2016;22:486-488	1.395
65	BOSSI P, BERGAMINI C, MICELI R, COVA A, ORLANDI E, RESTEGHINI C, LOCATI L, ALFIERI S, IMBIMBO M, GRANATA R, MARIANI L, IACOVELLI NA, HUBER V, CAVALLO A, LICITRA L, RIVOLTINI L.	Salivary Cytokine Levels and Oral Mucositis in Head and Neck Cancer Patients Treated With Chemotherapy and Radiation Therapy	International Journal Of Radiation Oncology Biology Physics 2016;96:959-966	4.495
66	BOSSI P, BERGAMINI C, Siano M, Cossu Rocca M, Spongini AP, FAVALES F, GIANNOCARO M, MARCHESI E, CORTELazzi B, PERRONE F, PILOTTI S, LOCATI LD, LICITRA L, CANEVARSI S, DE CECCO L.	Functional genomics uncover the biology behind the responsiveness of head and neck squamous cell cancer patients to cetuximab	Clinical Cancer Research 2016;22:3961-3970	8.738
67	BOSSI P, Farina D, GATTA G, Lombardi D, Nicolai P, ORLANDI E.	Paranasal sinus cancer	Critical Reviews In Oncology Hematology 2016;98:45-61	5.039
68	BOSSI P, ALFIERI S.	Investigational drugs for head and neck cancer	Expert Opinion On Investigational Drugs 2016;25:797-810	4.408
69	BOSSI P, RESTEGHINI C, PAIELLI N, LICITRA L, PILOTTI S, PERRONE F.	Prognostic and predictive value of EGFR in head and neck squamous cell carcinoma	Oncotarget 2016;7:74362-74379	5.008

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2016

	AUTHORS	TITLE	JOURNAL	I.F.
70	Bozzetti F, Paladini I, Rabaiotti E, Franceschini A, Alfieri V, Chetta A, Crisafulli E, Silva M, PASTORINO U, Sverzellati N.	Are interstitial lung abnormalities associated with COPD? A nested case-control study	International Journal Of Chronic Obstructive Pulmonary Disease 2016;11:1087-1096	3.046
71	BOZZI F, BRICH S, DAGRADA GP, NEGRI T, CONCA E, CORTELAZZI B, BELFIORE A, PERRONE F, GUALENI AV, GLOGHINI A, CABRAS A, Brenca M, Maestro R, ZAFFARONI N, CASALI P, BERTULLI R, DERACO M, PIOLLOTTI S.	Epithelioid peritoneal mesothelioma: A hybrid phenotype within a mesenchymal-epithelial/epithelial-mesenchymal transition framework	Oncotarget 2016;7:75503-75517	5.008
72	Bravi F, Wiens F, DECARLI A, Dal Pont A, Agostoni C, Ferraroni M.	Impact of maternal nutrition on breast-milk composition: A systematic review	American Journal Of Clinical Nutrition 2016;104:646-662	6.703
73	Bregní G, GALLI G, GEVORGIAN A, DE BRAUD F, DI COSIMO S.	Trastuzumab cardiac toxicity: A problem we put our heart into	Tumori 2016;102:1-5	1.071
74	Brennan B, De Salvo GL, Orbach D, De Paoli A, Kelsey A, Mudry P, Francotte N, Van Noesel M, Bisogno G, CASANOVA M, FERRARI A.	Outcome of extracranial malignant rhabdoid tumours in children registered in the European Paediatric Soft Tissue Sarcoma Study Group Non-Rhabdomyosarcoma Soft Tissue Sarcoma 2005 Study - EpSSG NRSTS 2005	European Journal Of Cancer 2016;60:69-82	6.163
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76	Bruinsma SM, Bangma CH, Carroll PR, Leapman MS, Rannikko A, Petrides N, Weerakoon M, Bokhorst LP, Roobol MJ, Movember Gap3 Consortium. {Valdagni R}.	Active surveillance for prostate cancer: A narrative review of clinical guidelines	Nature Reviews Urology 2016;13:151-167	5.957
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157	De Kock L, Boshari T, MARTINELLI F, Wojcik E, Niedziela M, Foulkes WD.	Adult-Onset Cervical Embryonal Rhabdomyosarcoma and DICER1 Mutations	Journal Of Lower Genital Tract Disease 2016;20:e8-e10	1.936
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301	INDINI A, DI NICOLA M, DEL VECCHIO M, DE BRAUD F.	Immune suppression and response to ipilimumab: Assessing Risk-to-Benefit ratio	Journal Of Clinical Oncology 2016;34:1017-1018	20.982
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318	LANDONI E, Ambrogi F, MARIANI L, MICELI R.	Parametric and nonparametric two-sample tests for feature screening in class comparison: A simulation study	Epidemiology Biostatistics And Public Health 2016;13:	0
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321	Lassale C, Gunter MJ, Romaguera D, Peelen LM, Van Der Schouw YT, Beulens JW, Freisling H, Muller DC, Ferrari P, Huybrechts I, Fagherazzi G, Boutron Ruault MC, Affret A, Overvad K, Dahm CC, Olsen A, Roswall N, Tsilidis KK, Katzke VA, Kuhn T, et al. [Agnoli C].	Diet quality scores and prediction of all-cause, cardiovascular and cancer mortality in a pan-european cohort study	Plos One 2016;11:e0159025	3.057
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340	Locke JA, Pond GR, Sonpavde G, NECCHI A, GIANNATEMPO P, Paluri RK, Niegisch G, Albers P, Buonera C, Di Lorenzo G, Vaishampayan UN, North SA, Agarwal N, Hussain SA, Pal S, Eigl BJ.	Cisplatin- Versus Non-Cisplatin-based First-Line Chemotherapy for Advanced Urothelial Carcinoma Previously Treated With Perioperative Cisplatin	Clinical Genitourinary Cancer 2016;14:331-340	2.599
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344	Lonardi S, Sobrero A, Rosati G, DI BARTOLOMEO M, Ronzoni M, Aprile G, Scartozzi M, Banzi M, Zampino MG, Pasini F, Marchetti P, Cantore M, Zaniboni A, Rimassa L, Ciuffreda L, Ferrari D, Barni S, Zagonel V, Maiello E, Rulli E, et al.	Phase III trial comparing 3-6months of adjuvant FOLFOX4/XELOX in stage II-III colon cancer: Safety and compliance in the TOSCA trial	Annals Of Oncology 2016;27:2074-2081	9.269
345	LOPERGOLO A, Perrone R, TORTORETO M, Doria F, BERETTA GL, ZUCO V, Freccero M, BORRELLO MG, LANZI C, Richter SN, ZAFFARONI N, FOLINI M.	Targeting of RET oncogene by naphthalene diimide-mediated gene promoter G-quadruplex stabilization exerts anti-tumor activity in oncogene-addicted human medullary thyroid cancer	Oncotarget 2016;7:49649-49663	5.008
346	LORUSSO D, PEROTTO S.	Ovarian cancer treatment in mutation carriers/brcaness	Minerva Ginecologica 2016;68:566-578	0

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348	LO RUSSO G, PUSCEDDU S, PROTO C, MACERELLI M, SIGNORELLI D, VITALI M, GANZINELLI M, GALLUCCI R, ZILEMBO N, PLATANIA M, BUZZONI R, DE BRAUD F, GARASSINO MC.	Treatment of lung large cell neuroendocrine carcinoma	Tumor Biology 2016;37:7047-7057	2.926
349	LO RUSSO G, PUSCEDDU S, Prinzi N, IMBIMBO M, PROTO C, SIGNORELLI D, VITALI M, GANZINELLI M, MACCAURO M, BUZZONI R, SEREGNI E, DE BRAUD F, GARASSINO MC.	Peptide receptor radionuclide therapy: focus on bronchial neuroendocrine tumors	Tumor Biology 2016;37:12991-13003	2.926
350	LO RUSSO G, PROTO C, GARASSINO MC.	Afatinib in the treatment of squamous non-small cell lung cancer: a new frontier or an old mistake?	Translational Lung Cancer Research 2016;5:110-114	0
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353	Lozneanu L, PINCIROLI P, Ciobanu DA, CARCANGIU ML, CANEVARO S, TOMASSETTI A, Caruntu ID.	Computational and immunohistochemical analyses highlight axl as a potential prognostic marker for ovarian cancer patients	Anticancer Research 2016;36:4155-4163	1.895
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356	Lu Y, Cross AJ, Murphy N, Freisling H, Travis RC, Ferrari P, Katzke VA, Kaaks R, Olsson A, Johansson I, Renstrom F, Panico S, PALA V, Palli D, Tumino R, Peeters PH, Siersema PD, Bueno De Mesquita HB, Trichopoulou A, Klinaki E, et al.	Comparison of abdominal adiposity and overall obesity in relation to risk of small intestinal cancer in a European Prospective Cohort	Cancer Causes & Control 2016;27:919-927	2.68
357	Lynch PM, Morris JS, Wen S, Advani SM, Ross W, Chang GJ, Rodriguez Bigas M, Raju GS, Ricciardiello L, Iwama T, Rossi BM, Pellise M, Stoffel E, Wise PE, BERTARIO L, Saunders B, Burt R, Belluzzi A, Ahnen D, Matsubara N, et al.	A proposed staging system and stage-specific interventions for familial adenomatous polyposis	Gastrointestinal Endoscopy 2016;84:115-125 e4	6.217



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359	MACCAURO M, LORENZONI A, CRIPPA F, Manca G, Chondrogiannis S, Giammarile F, Colletti PM, Cook GJ, Rubello D.	Sentinel Lymph Node Biopsy in Pelvic Tumors	Clinical Nuclear Medicine 2016;41:e288-e293	4.278
360	MACERELLI M, GANZINELLI M, Gouedard C, Broggini M, GARASSINO MC, Linardou H, Damia G, Wiesmuller L.	Can the response to a platinum-based therapy be predicted by the DNA repair status in non-small cell lung cancer?	Cancer Treatment Reviews 2016;48:8-19	7.983
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483	PELOSI G, GASPARINI P, CONTE D, FABBRI A, PERRONE F, TAMBORINI E, PUPA SM, CIRAVOLO V, CASERINI R, Rossi G, Cavazza A, Papotti M, Nakatani Y, Maisonneuve P, PASTORINO U, SOZZI G.	Synergistic activation upon MET and ALK coamplification sustains targeted therapy in sarcomatoid Carcinoma, a deadly subtype of lung cancer	Journal Of Thoracic Oncology 2016;11:718-728	5.04
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496	Petrelli F, Coinu A, Zaniboni A, PIETRANTONIO F, Barni S.	Prognostic factors after R0 resection of colorectal cancer liver metastases: A systematic review and pooled-analysis	Reviews On Recent Clinical Trials 2016;11:56-62	0
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629	Sugarbaker PH, Turaga KK, Alexander HR Jr, DERACO M, Hesdorffer M.	Management of malignant peritoneal mesothelioma using cytoreductive surgery and perioperative chemotherapy	Journal Of Oncology Practice 2016;12:928-935	0
630	Sverzellati N, Silva M, CALARESO G, Galeone C, MARCHIANÒ A, SESTINI S, SOZZI G, PASTORINO U.	Low-dose computed tomography for lung cancer screening: comparison of performance between annual and biennial screen	European Radiology 2016;26:3821-3829	3.64
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657	VENERONI S, DUGO M, DAIDONE MG, Iorio E, VALERI B, PINCIROLI P, DE BORTOLI M, MARCHESI E, MIODINI P, TAVERNA E, Ricci A, CANEVARI S, PELOSI G, BONGARZONE I.	Applicability of Under Vacuum Fresh Tissue Sealing and Cooling to Omics Analysis of Tumor Tissues	Biopreservation And Biobanking 2016;14:480-490	1.804
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659	VERDERIO P, BOTTELLI S, PIZZAMIGLIO S, CINISELLI CM.	Developing miRNA signatures: A multivariate prospective	British Journal Of Cancer 2016;115:1-4	5.569
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669	Vitale M, Masulli M, Cocozza S, Anichini R, Babini AC, Boemi M, Bonora E, Buzzetti R, Carpinteri R, Caselli C, Ceccarelli E, Cignarelli M, Citro G, Clemente G, Consoli A, Corsi L, De Gregorio A, Di Bartolo P, Di Cianni G, Fontana L, et al. [Grioni S, Krogh V].	Sex differences in food choices, adherence to dietary recommendations and plasma lipid profile in type 2 diabetes – The TOSCA. IT study	Nutrition Metabolism And Cardiovascular Diseases 2016;26:879-885	3.39
670	VITELLARO M, RICCI MT, BERTARIO L, SIGNORONI S.	Comment on Ueno et al: Prevalence of laparoscopic surgical treatment and its clinical outcomes in patients with familial adenomatous polyposis in Japan	International Journal Of Clinical Oncology 2016;21:1021-1022	1.806
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678	Wyszynski A, Hong CC, Lam K, Michailidou K, Lytle C, Yao S, Zhang Y, Bolla MK, Wang Q, Dennis J, Hopper JL, Southey MC, Schmidt MK, Broeks A, Muir K, Lophatananon A, Fasching PA, Beckmann MW, Peto J, Dos Santos Silva I, et al. [Radice P].	An intergenic risk locus containing an enhancer deletion in 2q35 modulates breast cancer risk by deregulating IGFBP5 expression	Human Molecular Genetics 2016;25:3863-3876	5.985
679	Yao JC, Fazio N, Singh S, BUZZONI R, Carnaghi C, Wolin E, Tomasek J, Raderer M, Lahner H, Voi M, Pacaud LB, Rouyre N, Sachs C, Valle JW, Delle Fave G, Van Cutsem E, Tesselaar M, Shimada Y, Oh DY, Strosberg J, et al.	Everolimus for the treatment of advanced, non-functional neuroendocrine tumours of the lung or gastrointestinal tract (RADIANT-4): A randomised, placebo-controlled, phase 3 study	Lancet 2016;387:968-977	44.002
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685	Zanardi E, GRASSI P, Cavo A, VERZONI E, MAGGI C, DE BRAUD F, Boccardo F, PROCOPIO G.	Treatment of elderly patients with metastatic renal cell carcinoma	Expert Review Of Anticancer Therapy 2016;16:323-334	2.094
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689	Zeng C, Guo X, Long J, Kuchenbaecker KB, Droit A, Michailidou K, Ghoussaini M, Kar S, Freeman A, Hopper JL, Milne RL, Bolla MK, Wang Q, Dennis J, Agata S, Ahmed S, Aittomaki K, Andrusis IL, Anton Culver H, Antonenkova NN, et al. [Manoukian S, Peissel B, Radice P].	Identification of independent association signals and putative functional variants for breast cancer risk through fine-scale mapping of the 12p11 locus	Breast Cancer Research 2016;18:64	5.211
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691	Zhao Z, Wen W, Michailidou K, Bolla MK, Wang Q, Zhang B, Long J, Shu XO, Schmidt MK, Milne RL, García Closas M, Chang Claude J, Lindstrom S, Bojesen SE, Ahsan H, Aittomaki K, Andrusis IL, Anton Culver H, Arndt V, Beckmann MW, et al. [Manoukian S].	Association of genetic susceptibility variants for type 2 diabetes with breast cancer risk in women of European ancestry	Cancer Causes & Control 2016;27:679-693	2.68
692	Zinzani PL, Pellegrini C, Cerciello G, Monaco F, Volpetti S, Peli A, Angelucci E, CORRADINI P, Cox MC, Guarini A, Musso M, Bresciani P, Amato G, Billio A, Caparrotti G, Figueira A, Nassi L, Gaudio F, Grossi A, Onida F, et al.	Romidepsin in relapsed/refractory T-cell lymphomas: Italian experience and results of a named patient program	Leukemia & Lymphoma 2016;57:2370-2374	3.093
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2	AGNOLI C, GRIONI S, PALA V, Allione A, Matullo G, Gaetano CD, TAGLIABUE G, SIERI S, KROGH V.	Biomarkers of inflammation and breast cancer risk: A case-control study nested in the EPIC-Varese cohort	Scientific Reports 2017;7:12708	4.259
3	AGNOLI C, Baroni L, Bertini I, Ciappellano S, Fabbri A, Papa M, Pellegrini N, Sbarbatì R, Scarino ML, Siani V, SIERI S.	Position paper on vegetarian diets from the working group of the Italian Society of Human Nutrition	Nutrition Metabolism And Cardiovascular Diseases 2017;27:1037-1052	3.679
4	AGRESTI R, SANDRI M, GENNARO M, BIANCHI G, MAUGERI I, RAMPA M, CAPRI G, CARCANGIU ML, TRECATE G, RIGGIO E, LOZZA L, DE BRAUD F.	Evaluation of Local Oncologic Safety in Nipple-Areola Complex-sparing Mastectomy After Primary Chemotherapy: A Propensity Score-matched Study	Clinical Breast Cancer 2017;17:219-231	2.816
5	Ahrens W, Siani A, Adan R, De Henauw S, Eiben G, Gwozdz W, Hebestreit A, Hunsberger M, Kaprio J, KROGH V, Lissner L, Molnar D, Moreno LA, Page A, Pico C, Reisch L, Smith RM, Tornaritis M, Veidebaum T, Williams G, et al.	Cohort Profile: The transition from childhood to adolescence in European children-how I.Family extends the IDEFICS cohort	International Journal Of Epidemiology 2017;46:1394-1395j	7.738
6	Alberio T, Pieroni L, Ronci M, Banfi C, BONGARZONE I, Bottone P, Brioschi M, Caterino M, Chinello C, Cormio A, Cozzolino F, Cunsolo V, Fontana S, Garavaglia B, Giusti L, Greco V, Lucacchini A, Maffioli E, Magni F, Monteleone F, et al.	Toward the Standardization of Mitochondrial Proteomics: The Italian Mitochondrial Human Proteome Project Initiative	Journal Of Proteome Research 2017;16:4319-4329	4.268
7	Aldrighetti L, Ratti F, Cillo U, Ferrero A, Ettorre GM, Guglielmi A, Giulianite F, Calise F, On Behalf Of The Italian Group Of Minimally Invasive Liver Surgery (I Go MILS). {Mazzaferrro V, Romito R}.	Diffusion, outcomes and implementation of minimally invasive liver surgery: a snapshot from the I Go MILS (Italian Group of Minimally Invasive Liver Surgery) Registry	Updates In Surgery 2017;69:271-283	0
8	Aleksandrova K, Schlesinger S, Fedirko V, Jenab M, Bueno De Mesquita B, Freisling H, Romieu I, Pischeddu T, Kaaks R, Gunter MJ, Dahm CC, Overvad K, Rostgaard Hansen AL, Tjonneland A, Trichopoulou A, Bamia C, Lagiou P, AGNOLI C, Mattiello A, Bradbury K, et al.	Metabolic mediators of the association between adult weight gain and colorectal cancer: Data from the european prospective investigation into cancer and nutrition (EPIC) cohort	American Journal Of Epidemiology 2017;185:751-764	4.825
9	Aleksandrova K, Jenab M, Leitzmann M, Bueno De Mesquita B, Kaaks R, Trichopoulou A, Bamia C, Lagiou P, Rinaldi S, Freisling H, Carayol M, Pischeddu T, Drogan D, Weiderpass E, Jakszyn P, Overvad K, Dahm CC, Tjonneland A, Boutou Ruault MC, Kuhn T, et al. [Agnoli C].	Physical activity, mediating factors and risk of colon cancer: insights into adiposity and circulating biomarkers from the EPIC cohort.	International Journal Of Epidemiology 2017;46:1823-1835	7.738
10	ALFIERI S, ORLANDI E, BOSSI P.	The Case Volume Issue in Head and Neck Oncology	Current Treatment Options In Oncology 2017;18:65	2.82
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24	APPIERTO V, DI COSIMO S, REDUZZI C, PALA V, CAPPELLETTI V, DAIDONE MG.	How to study and overcome tumor heterogeneity with circulating biomarkers: The breast cancer case	Seminars In Cancer Biology 2017;44:106-116	9.141
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61	BOGANI G, MARTINELLI F, DITTO A, SIGNORELLI M, TAVERNA F, LOMBARDO C, CHIAPPA V, LEONE ROBERTI MAGGIORE U, RECALCATI D, SCAFFA C, PEROTTO S, SABATUCCI I, INDINI A, LORUSSO D, RASPAGLIESI F.	The association of pre-treatment HPV subtypes with recurrence of VIN	European Journal Of Obstetrics & Gynecology And Reproductive Biology 2017;211:37-41	1.666
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210	Falcone F, Scambia G, Benedetti Panici P, SIGNORELLI M, Cormio G, Giorda G, Bogliolo S, Marinaccio M, Ghezzi F, Rabaiotti E, Breda E, Casella G, Fanfani F, Di Donato V, LEONE ROBERTI MAGGIORE U, Greggi S.	Tertiary cytoreductive surgery in recurrent epithelial ovarian cancer: A multicentre MITO retrospective study	Gynecologic Oncology 2017;147:66-72	4.959
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294	GRONCHI A, Maki RG, Jones RL.	Treatment of soft tissue sarcoma: A focus on earlier stages	Future Oncology 2017;13:13-21	2.131
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316	IACOVELLI NA, NAIMO S, BONFANTINI F, CAVALLO A, BOSSI P, FALLAI C, PIGNOLI E, ALFIERI S, BERGAMINI C, FAVALES F, ORLANDI E.	Preemptive treatment with Xonrid®, a medical device to reduce radiation induced dermatitis in head and neck cancer patients receiving curative treatment: a pilot study	Supportive Care In Cancer 2017;25:1787-1795	2.698
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325	Jakszyn P, Fonseca Nunes A, Lujan Barroso L, Aranda N, Tous M, Arjia V, Cross A, Bueno De Mesquita HBA, Weiderpass E, Kuhn T, Kaaks R, Sjoberg K, Ohlsson B, Tumino R, Palli D, Ricceri F, Fasanelli F, KROGH V, Mattiello A, Jenab M, et al.	Hepcidin levels and gastric cancer risk in the EPIC-EurGast study	International Journal Of Cancer 2017;141:945-951	6.513
326	Janssen ML, Van Broekhoven DL, Cates JM, Brammer WM, Nuyttens JJ, GRONCHI A, Salas S, Bonvalot S, Grunhagen DJ, Verhoef C.	Meta-analysis of the influence of surgical margin and adjuvant radiotherapy on local recurrence after resection of sporadic desmoid-type fibromatosis	British Journal Of Surgery 2017;104:347-357	5.899
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337	Khaniabadi YO, Polosa R, Chuturkova RZ, Daryanoosh M, Goudarzi G, BORGINI A, TITTARELLI A, Basiri H, Armin H, Nourmoradi H, Babaei AA, Naserian P.	Human health risk assessment due to ambient PM10 and SO2 by an air quality modeling technique	Process Safety And Environmental Protection 2017;111:346-354	2.905
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340	Kohli JS, TOLOMIO E, FRIGERIO S, MAURICHI A, RODOLFO M, Bennett DC.	Common Delayed Senescence of Melanocytes from Multiple Primary Melanoma Patients	Journal Of Investigative Dermatology 2017;137:766-768	6.287
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343	Kuchenbaecker KB, McGuffog L, Barrowdale D, Lee A, Soucy P, Dennis J, Domchek SM, Robson M, Spurdle AB, Ramus SJ, Mavaddat N, Terry MB, Neuhausen SL, Schmutzler RK, Simard J, Pharoah PDP, Offit K, Couch FJ, Chenevix Trench G, Easton DF, et al. [Azzollini J, Manoukian S, Peissel B, Radice P].	Evaluation of Polygenic Risk Scores for Breast and Ovarian Cancer Risk Prediction in BRCA1 and BRCA2 Mutation Carriers. Jnci-journal Of The National Cancer Institute 2017;109:djw302	Jnci-journal Of The National Cancer Institute 2017;109:djw302	12.589
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536	Pulito C, Mori F, Sacconi A, Goeman F, Ferraiuolo M, PASANISI P, Campagnoli C, BERRINO F, Fanciulli M, Ford RJ, Levrero M, Pediconi N, Ciuffreda L, Milella M, Steinberg GR, Cioce M, Muti P, Strano S, Blandino G.	Metformin-induced ablation of microRNA 21-5p releases Sestrin-1 and CAB39L antitumoral activities	Cell Discovery 2017;3:17022	0
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544	RANCATI T, PALORINI F, Cozzarini C, Fiorino C, VALDAGNI R.	Understanding urinary toxicity after radiotherapy for prostate cancer: First steps forward	Tumori 2017;103:395-404	1.233
545	Rancoita PM, Valberg M, DEMICHELI R, BIGANZOLI E, Di Serio C.	Tumor dormancy and frailty models: A novel approach	Biometrics 2017;73:260-270	1.329
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549	RASPAGLIESI F, BOGANI G, DITTO A, MARTINELLI F, CHIAPPA V, BORGHI C, SCAFFA C, MORANO F, MALTESE G, LORUSSO D.	Implementation of Extensive Cytoreduction Resulted in Improved Survival Outcomes for Patients with Newly Diagnosed Advanced-Stage Ovarian, Tubal, and Peritoneal Cancers	Annals Of Surgical Oncology 2017;24:3396-3405	4.041
550	RASPAGLIESI F, BOGANI G, MARTINELLI F, SIGNORELLI M, SCAFFA C, SABATUCCI I, LORUSSO D, DITTO A.	3D vision improves outcomes in early cervical cancer treated with laparoscopic type B radical hysterectomy and pelvic lymphadenectomy	Tumori 2017;103:76-80	1.233



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554	Reni M, Mazza E, Zanon S, GATTA G, Vecht CJ.	Central nervous system gliomas	Critical Reviews In Oncology Hematology 2017;113:213-234	4.971
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566	Ross MW, Cescon M, Angelico R, Andorno E, Rossi G, Pinna A, De Carlis L, Baccarani U, Cillo U, Colledan M, MAZZAFERRO V, Tisone G, Rossi M, Tuzzolino F, Pagano D, Gruttaduria S, Mazariegos G, Gridelli B, Spada M.	A matched pair analysis of multicenter longterm follow-up after split-liver transplantation with extended right grafts	Liver Transplantation 2017;23:1384-1395	3.91
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579	SAPONARA M, STACCHIOTTI S, GRONCHI A.	Pharmacological therapies for Liposarcoma	Expert Review Of Clinical Pharmacology 2017;10:361-377	2.932
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584	Sarink D, Schock H, Johnson T, Overvad K, Holm M, Tjønneland A, Boutron Ruault MC, His M, Kvaskoff M, Boeing H, Lagiou P, Papapetsta EM, Trichopoulou A, Palli D, PALA V, Mattiello A, Tumino R, Sacerdote C, Bueno De Mesquita HBA, Van Gils CH, et al.	Circulating RANKL and RANKL/OPG and breast cancer risk by ER and PR subtype: Results from the EPIC cohort	Cancer Prevention Research 2017;10:525-534	3.985
585	Sartore Bianchi A, PIETRANTONIO F, Amato A, MILIONE M, Cassingena A, Ghezzi S, CAPORALE M, BERENATO R, Falcomatà C, PELLEGRINELLI A, Bardelli A, Nichelatti M, Tosi F, DE BRAUD F, Di Nicolantonio F, Barault L, Siena S.	Digital PCR assessment of MGMT promoter methylation coupled with reduced protein expression optimises prediction of response to alkylating agents in metastatic colorectal cancer patients	European Journal Of Cancer 2017;71:43-50	6.029
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642	TAZZARI M, Indio V, Vergani B, DE CECCO L, RINI F, NEGRI T, CAMISASCHI C, FIORE M, STACCHIOTTI S, DAGRADA GP, CASALI PG, GRONCHI A, Astolfi A, Pantaleo MA, Villa A, LOMBARDO C, ARIENTI F, PILOTTI S, RIVOLTINI L, CASTELLI C.	Adaptive Immunity in Fibrosarcomatous Dermatofibrosarcoma Protuberans and Response to Imatinib Treatment	Journal Of Investigative Dermatology 2017;137:484-493	6.287



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660	Uhry Z, Bossard N, Remontet L, Iwaz J, Roche L, Grell Eurocare 5 Working Group And The Censur Working Survival Group, {Gatta G, Sant M, Amash H, Amati C, Baili P, Berrino F, Bonfarnuzzo S, Botta L, Di Salvo F, Foschi R, Margutti C, Meneghini E, Minicozzi P, Trama A, Tagliabue G, Contiero P}.	New insights into survival trend analyses in cancer population-based studies: the SUDCAN methodology	European Journal Of Cancer Prevention 2017;26 Trends in cancer net survival in six European Latin Countries: the SUDCAN study:S9-S15	2.556
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668	VENERONI L, BOSCHETTI L, BARRETTA F, CLERICI CA, SIMONETTI F, SCHIAVELLO E, BIASSONI V, SPREAFICO F, GANDOLA L, PECORI E, DILETTO B, Poggi G, GARIBOLDI F, SENSI R, MASSIMINO M.	Quality of life in long-term survivors treated for metastatic medulloblastoma with a hyperfractionated accelerated radiotherapy (HART) strategy	Childs Nervous System 2017;33:1969-1976	1.081
669	Verburg FA, Luster M, Giovanella L, Lassmann M, CHIESA C, Chouin N, Flux G, Eanm Thyroid, Radiation Protection And Dosimetry Committees.	The "reset button" revisited: why high activity ¹³¹ I therapy of advanced differentiated thyroid cancer after dosimetry is advantageous for patients	European Journal Of Nuclear Medicine And Molecular Imaging 2017;44:915-917	7.277
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672	Verwaal VJ, Rau B, Jamali F, Gilly FN, De Hingh I, Takala H, Syk I, Pelz J, Mulsow J, Van Der Speeten K, KUSAMURA S, Iversen LH, Mohamed F, Glehen O, Younan R, Yarema R, Gonzalez Moreno S, O'Dwyer S, Yonemura Y, Sugarbaker P.	Registries on peritoneal surface malignancies throughout the world, their use and their options	International Journal Of Hyperthermia 2017;33:528-533	3.262
673	VERZONI E, GRASSI P, RATTA R.	What advances have been made in immunotherapy for renal cell carcinoma?	Future Oncology 2017;13:665-668	2.131
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676	Vincenzi B, STACCHIOTTI S, COLLINI P, Pantano F, Rabitti C, Perrone G, Iuliani M, Baldi A, Badalamenti G, SANFILIPPO R, Santini D, Muda AO, GRONCHI A, CASALI P, Dei Tos AP, Tonini G.	Human equilibrative nucleoside transporter 1 gene expression is associated with gemcitabine efficacy in advanced leiomyosarcoma and angiosarcoma	British Journal Of Cancer 2017;117:340-346	6.176

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685	Walker LC, Marquart L, Pearson JF, Wiggins GA, O'Mara TA, Parsons MT, Bcfr, Barrowdale D, Mcguffog L, Dennis J, Benitez J, Slavin TP, RADICE P, Frost D, Embrace, Godwin AK, Meindl A, Schmutzler RK, Gemo Study Collaborators, Isaacs C, et al.	Evaluation of copy-number variants as modifiers of breast and ovarian cancer risk for BRCA1 pathogenic variant carriers	European Journal Of Human Genetics 2017;25:432-438	4.287
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691	Xylinas E, NECCHI A, Young Academic Urologists Urothelial Carcinoma Group Of The European Association Of Urology.	Re: Effectiveness of Adjuvant Chemotherapy After Radical Nephroureterectomy for Locally Advanced and/or Positive Regional Lymph Node Upper Tract Urothelial Carcinoma	European Urology 2017;72:473-474	16.265
692	Young RJ, Litire S, Lia M, Hogendoorn PCW, Fisher C, Mechtersheimer G, Daugaard S, Sciot R, Collin F, Messiou C, Grunwald V, GRONCHI A, Van Der Graaf W, Wardemann E, Judson I.	Predictive and prognostic factors associated with soft tissue sarcoma response to chemotherapy: a subgroup analysis of the European Organisation for Research and Treatment of Cancer 62012 study	Acta Oncologica 2017;56:1013-1020	3.156
693	Zamora Ros R, Castaneda J, Rinaldi S, Cayssials V, Slimani N, Weiderpass E, Tsilidis KK, Boutron Ruault MC, Overvad K, Eriksen AK, Tjønneland A, Kuhn T, Katzke V, Boeing H, Trichopoulou A, La Vecchia C, Kotanidou A, Palli D, GRIONI S, Mattiello A, et al.	Consumption of fish is not associated with risk of differentiated thyroid carcinoma in the European prospective investigation into cancer and nutrition (EPIC) study	Journal Of Nutrition 2017;147:1366-1373	4.145
694	Zamora Ros R, Barupal DK, Rothwell JA, Jenab M, Fedirko V, Romieu I, Aleksandrova K, Overvad K, Kyro C, Tjønneland A, Affret A, His M, Boutron Ruault MC, Katzke V, Kuhn T, Boeing H, Trichopoulou A, Naska A, Kritikou M, Saieva C, et al. [Agnoli C].	Dietary flavonoid intake and colorectal cancer risk in the European prospective investigation into cancer and nutrition (EPIC) cohort.	International Journal Of Cancer 2017;140:1836-1844	6.513
695	Zamora Ros R, Rothwell JA, Achaintre D, Ferrari P, Boutron Ruault MC, Mancini FR, Affret A, Kuhn T, Katzke V, Boeing H, Kuppel S, Trichopoulou A, Lagiou P, La Vecchia C, Palli D, CONTIERO P, Panico S, Tumino R, Ricceri F, Noh H, et al.	Evaluation of urinary resveratrol as a biomarker of dietary resveratrol intake in the European Prospective Investigation into Cancer and Nutrition (EPIC) study	British Journal Of Nutrition 2017;117:1596-1602	3.706
696	ZECCA E, BRUNELLI C, CENTURIONI F, MANZONI A, PIGNI A, CARACENI A.	Fentanyl sublingual tablets versus subcutaneous morphine for the management of severe cancer pain episodes in patients receiving opioid treatment: A double-blind, randomized, noninferiority trial	Journal Of Clinical Oncology 2017;35:759-765	24.008
697	Zheng JS, Sharp SJ, Immura F, Koulman A, Schulze MB, Ye Z, Griffin J, Guevara M, Huerta JM, Kroger J, Sluijs I, Agudo A, Barricarte A, Boeing H, Colorado Yohar S, Dow C, Dorronsoro M, Dinesen PT, Fagherazzi G, Franks PW, et al. [Tagliabue G].	Association between plasma phospholipid saturated fatty acids and metabolic markers of lipid, hepatic, inflammation and glycaemic pathways in eight European countries: A cross-sectional analysis in the EPIC-InterAct study.	Bmc Medicine 2017;15:203	8.097
698	Zini EM, Lanzola G, BOSSI P, Quaglini S.	An environment for guideline-based decision support systems for outpatients monitoring	Methods Of Information In Medicine 2017;56:283-293	1.772

PUBLICATIONS

2017

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699	Zinzani PL, Rigacci L, Cox MC, DEVIZZI L, Fabbri A, Zaja F, Di Rocco A, Rossi G, Storti S, Fattori PP, Argnani L, Vitolo U.	The efficacy of lenalidomide combination therapy in heavily pretreated non-Hodgkin lymphoma patients: an Italian observational, multicenter, retrospective study	Leukemia & Lymphoma 2017;58:226-229	2.755
700	Zotti P, Cocchi S, Polesel J, Cipolat Mis C, Bragatto D, Cavuto S, Conficconi A, Costanzo C, De Giorgi M, Drace CA, Fiorini F, GANGERI L, Lisi A, Martino R, Mosconi P, Paradiso A, Ravaioli V, Truccolo I, De Paoli P, Icpeg.	Cross-cultural validation of health literacy measurement tools in Italian oncology patients	Bmc Health Services Research 2017;17:410	1.827
701	Zucca E, Conconi A, Martinelli G, Bouabdallah R, Tucci A, Vitolo U, Martelli M, Pettengell R, Salles G, Sebban C, Guillermo AL, Pinotti G, DEVIZZI L, Morschhauser F, Tilly H, Torri V, Hohaus S, Ferreri AJM, Zachee P, Bosly A, et al.	Final Results of the IELSG-19 Randomized Trial of Mucosa-Associated Lymphoid Tissue Lymphoma: Improved Event-Free and Progression-Free Survival With Rituximab Plus Chlorambucil Versus Either Chlorambucil or Rituximab Monotherapy	Journal Of Clinical Oncology 2017;35:1905-1912	24.008
702	Zwarthoed C, El Galaly TC, Canepari M, Ouvrier MJ, Viotti J, Ettaiche M, VIVIANI S, Rigacci L, Trentin L, Rusconi C, Luminari S, Cantonetti M, Bolis S, Borra A, Darcourt J, Salvi F, Subocz E, Tajer J, Kulikowski W, Malkowski B, et al.	Prognostic value of bone marrow tracer uptake pattern in baseline PET scans in hodgkin lymphoma: Results from an international collaborative study	Journal Of Nuclear Medicine 2017;58:1249-1254	6.646





ONGOING CLINICAL STUDIES 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0024/16	"DianaWeb: before and after study online based participatory research to test whether lifestyle and diet are able to reduce the incidence of recurrences (local, remote) or secondary cancers, improve prognosis and survival of breast cancer"	A. Villarini	2016		-	2860	387	2473
INT 0032/03	Prognostic significance of blood concentrations of testosterone and insulin in women with early breast cancer	F. Berrino	2003		Observational	2467		
INT 0146/12	Pre-operative evaluation of distress thermometer in breast cancer patients	R. Agresti	2013		Observational	2200	400	0
INT 0037/07	Randomized trial of diet, physical activity and breast cancer recurrences: the DIANA-5 study	F. Berrino	2008	25/09/2017	-	1667		
INT 0076/08	Tevere project: primary prevention of breast cancer by diet, physical activity or Metformin assumption	F. Berrino	2009		III	622	73	50
INT 0195/15	Role of inorganic xenoestrogens and their binding proteins in risk of developing breast cancer subtypes	S. Sieri	2016		Observational	600	600	0
INT 0080/14	Role of inorganic xenoestrogens and their binding proteins in risk of developing breast cancer subtypes	G. Scaperrotta	2015		Observational	476	253	140
INT 0066/15	Identification of circulating markers for early diagnosis of breast carcinoma	E. Tagliabue	2015		Observational	290	125	110
INT 0036/16	Observational prospective survey on Oncotype DX Breast Cancer assays (ODX) use in the current clinical practice (PONDx)	G. V. Bianchi	2016	31/12/2017	Observational	163	46	Closed accrual
INT 0092/12	A randomized trial comparing sentinel lymph node biopsy vs no axillary surgical staging in patients with small breast cancer and a negative preoperative axillary assessment	R. Agresti	2013		-	154	24	Closed accrual
INT 0201/14	Identification of molecular markers predictive for Trastuzumab benefit	E. Tagliabue	2015		Observational	150	50	50



SCIENTIFIC REPORT 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0187/15	"Exploratory study on CD205 expression in solid tumors (triple negative breast cancer, pancreatic cancer and bladder cancer) using immunohistochemistry, fluorescence in situ hybridization analysis and gene sequencing: a retrospective observational investigation"	M. L. Carcangiu	2016		Observational	150	150	0
INT 0199/15	Monitoring disease progression in triple negative breast cancers by profiling liquid biopsies and tumor lesions	M. G. Daidone	2016		Observational	142	116	26
INT 0051/12	Identification of genes associated with toxicity from radiation in breast cancer patients	L. Lozza	2012		Observational	141		
INT 0171/15	Early-onset Breast Cancer: searching for epigenetic determinants	S. Manoukian	2016		Observational	111	111	0
INT 0051/14	Selective axillary dissection vs complete axillary dissection. Randomized controlled clinical trial to evaluate the prevention of lymphedema in breast cancer treatment	M. Gennaro	2014		-	110	26	23
INT 0193/15	Role of d16HER2 splice variant in breast cancer aggressiveness as a function of addiction to HER2 signaling	S. Manoukian	2016	01/09/2017	Observational	81	34	Closed accrual
INT 0186/13	Circulating miRNAs to predict outcome and to guide treatment of breast cancer patients on preoperative systemic therapy	S. Di Cosimo	2014	01/04/2017	Observational	65	5	Closed accrual
INT 0088/15	Personalized nutritional psychoeducational support associated with tocotrienols in women with pre-operative primary breast cancer	C. Ferraris	2016	10/07/2017	-	60	28	Closed accrual
INT 0007/15	Expanding the repertoire of genetic factors associated with hereditary susceptibility to breast cancer	P. Radice	2015		Observational	50	25	0
INT 0012/17	Role of mast cell infiltration in breast carcinoma and correlation with tumor outcome	M. P. Colombo	2017		Observational	48		48
INT 0159/15	"Biomechanical evaluation of the scapular girdle functional limitation and of fatigue in patients with lymphedema secondary to axillary dissection for breast cancer"	A. Balzarini	2016		-	40	18	Closed accrual
INT 0127/12	Impact of acellular dermal matrix in reduction of surgical complexity of breast reconstructions with implants	A. Spano	2013	31/07/2017	-	36	0	Closed accrual
INT 0109/12	SHARE - Cyberknife Partial Breast Irradiation for Early Stage Breast Cancer. A phase I prospective study	L. Lozza	2013		-	30	0	Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0148/15	Circulating miRNA and sensitivity to Gemcitabine in patients with metastatic breast cancer	S. Cresta	2016		Observational	27	13	14
INT 0026/13	Neoadjuvant chemotherapy with Nab-Paclitaxel in women with HER2-negative high-risk breast cancer ETNA (Evaluating Treatment with neoadjuvant Abraxane)	G. Mariani	2013		III	18		
INT 0108/15	A randomized double-blind, placebo-controlled study of Ribociclib in combination with Fulvestrant for the treatment of postmenopausal women with hormone receptor positive, her2-negative, advanced breast cancer who have received no or only one line of prior endocrine treatment	G. V. Bianchi	2015	07/12/2017	III	17	Closed accrual	
INT 0043/14	A randomized, multicenter, open-label, phase III trial comparing Trastuzumab plus Pertuzumab plus a Taxane following Anthracyclines versus Trastuzumab emtansine plus Pertuzumab following Anthracyclines as adjuvant therapy in patients with operable HER2-positive primary breast cancer	G. V. Bianchi	2014		III	16		
INT 0061/15	A randomized, multicenter, open-label, phase II trial to evaluate the efficacy and safety of Palbociclib in combination with Fulvestrant or Letrozole in patients with HER2 negative, ER+ metastatic breast cancer (PARSIFAL 1)	F. De Braud	2015		II	14	9	0
INT 0161/13	Modulation of the Immune System and Adjuvant Chemotherapy in Breast Cancer	S. Cresta	2014		-	12	0	0
INT 0079/16	Phase I/Ib, open label study of LSZ102 single agent and LSZ102 in combination with either LEE011 (LSZ102 + LEE011) or BYL719 (LSZ102 + BYL719) in patients with advanced or metastatic ER+ breast cancer who have progressed after endocrine therapy	F. De Braud	2016		I	12	3	9
INT 0030/15	A phase II, randomized, open-label, two-arm study to assess the efficacy and safety of the epigenetic modifying effects of CC-486 (oral Azacitidine) in combination with Fulvestrant in postmenopausal women with er+, her2- metastatic breast cancer who have progressed on an aromatase inhibitor	G. V. Bianchi	2015	20/11/2017	II	12	Closed accrual	



SCIENTIFIC REPORT 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0022/17	COMPLEEMENT-1: An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of Ribociclib (LEEO11) in combination with Letrozole for the treatment of men and pre/postmenopausal women with hormone receptor-positive (HR+) HER2-negative (HER2-) advanced breast cancer (aBC) with no prior hormonal therapy for advanced disease	G. V. Bianchi	2017		III	10		Closed accrual
INT 0049/13	Postmastectomy radiotherapy in reconstructed breast: evaluation of dose distribution in partially and completed inflated tissue expanders	L. Lozza	2013	01/12/2017	-	9	0	Closed accrual
INT 0153/14	A randomized trial comparing maintenance Aromatase Inhibitors (AIs) + Everolimus (Afinitor) vs. AIs in patients with HR+ metastatic breast cancer with disease control after first line chemotherapy	G. Mariani	2015		III	9	1	Closed accrual
INT 0029/14	PERtuzumab-trastuzumab plus lEtrozole In endocrine Sensitive breast cancer: a phase II neoAdjuvant study – PER ELISA	G. V. Bianchi	2014		II	7	1	Closed accrual
INT 0013/16	A Randomized Multicenter Pivotal Study of CDX-011 (CRO11-vcMMAE) in Patients with Metastatic, GPNMB Over-Expressing, Triple-Negative Breast Cancer (The "METRIC" Study)	G. V. Bianchi	2016		II	7	4	Closed accrual
INT 0179/15	Neo-Adjuvant study with the PDL1-directed antibody in Triple Negative Locally Advanced Breast Cancer undergoing treatment with Nab-Paclitaxel and Carboplatin	G. Mariani	2016		I/II	6	2	4
INT 0022/16	Study of gut microbiota in HER2-positive patients treated with Trastuzumab-containing therapy	E. Tagliabue	2016		Observational	6	3	3
INT 0055/13	A randomized, multicenter, open-label phase III study to evaluate the efficacy and safety of Trastuzumab Emtansine versus Trastuzumab as adjuvant therapy for patients with HER2-positive primary breast cancer who have residual tumor present pathologically in the breast or Axillary lymph nodes following preoperative therapy	G. V. Bianchi	2013		III	6		
INT 0042/16	Adjuvant treatment for high-risk triple negative breast cancer patients with the anti-PD-L1 antibody Avelumab: a phase III randomized trial	G. V. Bianchi	2017		III	5		5

ONGOING CLINICAL STUDIES 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0029/12	A phase III prospective, two-cohort non-randomized, multi-centre, multinational, open label study to assess the safety of asisted-and self-administered subcutaneous Trastuzumab as adjuvant therapy in patients with operable HER-2-positive early breast cancer	G. Mariani	2013		III	5		
INT 0174/13	Multicenter, randomized, double-blind, placebo-controlled, phase III trial of Fulvestrant (FASLODEX) with or without PD-0332991 (Palbociclib) ± Goserelin in women with hormone receptor-positive, HER2-negative metastatic breast cancer whose disease progressed after prior endocrine therapy	G. V. Bianchi	2014		III	5		
INT 0138/17	Use of Peak Plasmablade in implant-based breast reconstruction after radiotherapy	U. Cortinovis	2017		-	4		4
INT 0078/12	A phase III randomized, double blind placebo controlled study of BKM120 with Fulvestrant, in postmenopausal women with hormone receptor-positive HER2-negative locally advanced or metastatic breast cancer which progressed on or after aromatase inhibitor treatment (BELL-E-2)	F. De Braud	2013	02/02/2017	III	4		
INT 0090/14	A randomized double-blind, placebo-controlled study of LEE011 in combination with Letrozole for the treatment of postmenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer who received no prior therapy for advanced disease	G. V. Bianchi	2014		III	4		
INT 0101/17	A phase II, multicenter,open-label, two-cohort, noncomparative study to assess the efficacy and safety of Alpelisib plus Fulvestrant or Letrozole in patients with PIK3CA mutant, hormone receptor (HR) positive, HER2-negative advanced breast cancer (aBC), who have progressed on or after CDK 4/6 inhibitor treatment	G. V. Bianchi	2017		II	3		3
INT 0173/14	A phase II randomized, double-blind study of neoadjuvant Letrozole plus GDC-0032 versus Letrozole plus placebo in postmenopausal women with er-positive/her2-negative, early stage breast cancer	S. Di Cosimo	2015	12/07/2017	II	3	Closed accrual	
INT 0116/14	A randomized, phase II, multicenter, placebo-controlled study of Ipatasertib (GDC-0068), an inhibitor of AKT, in combination with Paclitaxel as front-line treatment for patients with metastatic triple-negative breast cancer TRIPLE-NEGATIVE BREAST CANCER	F. De Braud	2015		II	3	Closed accrual	



SCIENTIFIC REPORT 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0126/17	A phase III, multicenter, randomised, double-blind, placebo-controlled study of Atezolizumab (anti-pd-l1 antibody) in combination with Paclitaxel compared with placebo with Paclitaxel for patients with previously untreated inoperable locally advanced or metastatic triple negative breast cancer	G. V. Bianchi	2017		III	2		2
INT 0015/13	Ex-vivo evaluation of the surgical specimen by MRI in breast cancer and randomized study comparing MRI and conventional radiography in non-palpable lesions	R. Agresti	2015		-	1	0	0
INT 0101/11	Effect of oral red clover on the symptoms of menopausal syndrome induced by adjuvant hormonal treatment in women with a diagnosis of breast cancer	C. Ferraris	2012	28/06/2016	IV	88		
INT 0102/11	A randomized, two-arm, open label, multicenter phase II trial assessing the efficacy and safety of Pertuzimab given in combination with Trastuzumab plus an aromatase inhibitor in first line patients with HER 2-positive and hormone receptor-positive advanced (metastatic and locally advanced) breast cancer	G. V. Bianchi	2012	23/09/2016	II	2		
INT 0081/12	A randomized, blinded, single center study to assess the incidence of surgical site infections in breast cancer surgery after preoperative skin preparation with Chlorhexidine 2% in Alcohol 70% (CHLORAPREP ®) versus 10% Povidone-Iodine	M. Langer	2013	05/09/2016	IV	2.160	Closed accrual	
INT 0125/12	A two-cohort, open-label, multicenter, study of Trastuzumab Emtansine (T-DM1) in HER2 positive locally advanced or metastatic breast cancer patients who have received prior anti-HER2 and chemotherapy-based treatment	G. V. Bianchi	2013	13/10/2016	III	5		
INT 0001/13	A phase II, open label, single arm trial of neoadjuvant therapy in patients with triple negative breast cancer evaluating the efficacy of Eribulin mesylate following Anthracycline and Taxane and correlative science studies attempting to identify predictors of response (HOPE Study)	F. De Braud	2013	13/06/2016	II	8	Closed accrual	
INT 0071/13	A multicenter randomised trial of contrast-enhanced MR imaging as a breast cancer screening tool alternative to mammography and ultrasonography in women at intermediate risk. Feasibility, and short term results. (MRIB Trial)	P. Panizza	2014	31/08/2016	-	72		

ONGOING CLINICAL STUDIES 2016-2017

BREAST CARCINOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0106/13	Randomized controlled trial of diet and physical activity in carriers of BRCA mutation	P. Pasanisi	2013	31/12/2016	-	260	Closed accrual	
INT 0111/13	Assessment of breast cancer progression risk based on extracellular matrix characteristics	E. Tagliabue	2013	31/12/2016	Observational	274	Closed accrual	
INT 0136/13	FINESSE - An open, 3-cohort, phase II trial testing oral administration of Lucitanib in patients with FGFR1-amplified or non-amplified oestrogen receptor positive metastatic breast cancer	F. De Braud	2014	01/02/2016	II	4	Closed accrual	
INT 0145/13	Biomarkers and breast cancer risk prediction in younger women	V. Krogh	2014	31/12/2016	Observational	260	Closed accrual	
INT 0165/13	Observational study to assess the impact of hormonal treatment with aromatase inhibitors on the psychological dimension of patients with breast cancer	C. Borreani	2013	30/06/2016	Observational	45		
INT 0030/14	Use of laser scanner volumeter in breast cancer upper arm lymphedema	A. Balzarini	2014	22/04/2016	-	200	Closed accrual	
INT 0100/14	Assessment of the performance of tomosynthesis in women eligible for or subjected to Breast Conserving Treatment for invasive breast cancer	C. Ferranti	2014	30/06/2016	Observational	548	Closed accrual	
INT 0144/14	"Role of extracellular matrix components in progression of breast cancer"	E. Tagliabue	2015	31/12/2016	Observational	200	Closed accrual	
INT 0067/15	1-stage implant-based versus 2-stage expander-based reconstruction of the breast	E. Riggio	2015	30/12/2016	Observational	280	Closed accrual	
INT 0015/16	Observational, retrospective study to evaluate the clinical activity and tolerability of combination of Everolimus and Exemestane in advanced HR+ breast cancer patients	G. V. Bianchi	2016	31/07/2016	Observational	55	Closed accrual	
INT 0134/16	Risks of complications in immediate reconstruction during primary treatment of breast cancer	E. Riggio	2016	27/12/2016	Observational	262	Closed accrual	
INT 0196/14	Institutional clinical registry for breast cancer	M. Sant	2015		-	3431	1081	1059
INT 0203/14	Study of the role of adipocytes in the development and progression of breast cancer	T. Triulzi	2015		-	47	20	17
INT 0128/14	Cardiac Oncology Toxicity in Breast Cancer (ESC-COT) EACVIC-HFA Pilot Registry	P. Piotti	2015	31/12/2016	-	1	0	



SCIENTIFIC REPORT 2016-2017

GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0003/13	Identification of Genetic Circulating Biomarkers for the Early Diagnosis of Colorectal Cancer and its benign precursors in patients at increased risk	M. Gariboldi	2013		Observational	1220	328	280
INT 0036/13	Identification of Genetic Circulating Biomarkers for monitoring and early detection of recurrence in surgically treated colorectal Cancer patients	M. Gariboldi	2013		Observational	449	131	85
INT 0117/15	Explorative Evaluation of new potential prognostic factor in patient with gastrointestinal cancer	F. De Braud	2015		Observational	360	178	120
INT 0021/16	Observational Retrospective Study on Prognostic Relevance of NENs classification at the light of recent literature evidences concerning morphology, immunophenotype and molecular features with focus on Role of Immunologic Factors in NENs prognosis	M. Milione	2016		Observational	318	318	0
INT 0110/13	IL-6-related inflammation signatures as a predictive marker of recurrence in liver cancer patients	V. Mazzaferro	2013		Observational	248	38	Closed accrual
INT 0198/16	A comparison of patient population, surgical resection, adjuvant treatment, and outcome among patients with pancreatic cancer – a study among EurocanPlatform members	M. Sant	2017	31/01/2017	Observational	177		Closed accrual
INT 0015/17	The current role of surgery in the treatment of anal squamous cell carcinoma	F. Belli	2017	10/07/2017	Observational	150		Closed accrual
INT 0052/07	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	M. Di Bartolomeo	2007		III	131		
INT 0006/12	Efficacy of tandem treatment with [90Y-DOTA, Tyr(3)] Octreotide and [177LuDOTA, Tyr(3)] Octreotide in patients with neuroendocrine tumour overexpressing somatostatin receptors and refractory to conventional therapy	E. Seregni	2013	31/12/2017	II	122	34	Closed accrual
INT 0117/12	Identification of circulating biomarkers of resistance to antiangiogenic treatment in patients with advanced colorectal cancer and assessment of their modification during therapy with antiangiogenic drugs (Bevacizumab, Aflibercept and Regorafenib)	F. De Braud	2013		Observational	103		
INT 0079/09	Observational study of plasma levels of Imatinib in patients with gastrointestinal stromal tumor	P. G. Casali	2010		Observational	85		

ONGOING CLINICAL STUDIES 2016-2017

GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0020/13	Retrospective observational study on the use of off-label Temozolamide in patients with metastatic colorectal cancer with methylation of the MGMT gene	M. Di Bartolomeo	2013	31/12/2017	Observational	69	0	Closed accrual
INT 0126/13	Observational study on the impact of genetic polymorphisms on the occurrence of chemotherapy-induced toxicity in gastrointestinal epithelial neoplasms	F. De Braud	2013		Observational	53	1	0
INT 0071/16	Investigating the aetiology of Oesophageal and Gastric Cancer: the Role of Hormones	V. Krogh	2016	30/11/2017	Observational	53	53	Closed accrual
INT 0101/14	Role of the natural fluorescence of human blood plasma in patients with colorectal cancer: study of the correlation between the clinical evolution of the disease and the native fluorescence, and qualitative identification of the responsible agents	E. Leo	2014	01/01/2017	Observational	52		
INT 0070/15	First-line FOLFOX-4 Plus Panitumumab followed by 5-FU/LV Plus Panitumumab or single-agent Panitumumab as maintenance therapy in patients with RAS wild-type, metastatic colorectal cancer: the VALENTINO study	F. De Braud	2015		II	48	28	Closed accrual
INT 0050/13	Perioperative treatment with COI-B (Capecitabine, Oxaliplatin, Irinotecan and Bevacizumab) of high risk or borderline resectable colorectal cancer liver metastases	F. De Braud	2013		II	46	15	Closed accrual
INT 0177/14	Detection of circulating tumor cells and ct DNA blood levels in patients with advanced intra- and extra-hepatic cholangiocarcinoma and evaluation of their changes during treatment	L. Celio	2014		Observational	41	13	12
INT 0158/15	Evaluation of the disease outcome after viral clearance (sustained virological response, SVR) in patients with HCV-related cirrhosis, marginally compensated or decompensated, treated with direct antiviral agents (DAAs) without IFN	V. Mazzaferro	2016		Observational	39	38	1
INT 0031/12	Peritoneal Mesothelioma: Optimize Outcomes by the Integration of new Prognostic Factors and Potential Therapeutic Targets in a Individualized Treatment based on Molecular Characterization and Chemosensitivity Profile on Primary Cultures	M. Deraco	2012		II	38		



GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0011/05	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	P. G. Casali	2005	23/09/2017	III	36		
INT 0080/09	Controlled extension of conventional criteria for liver transplantation in hepatocellular carcinoma (HCC): a prospective validation study	V. Mazzaferro	2010		II/III	35		
INT 0074/15	First-line FOLFOXIRI plus Bevacizumab followed by reintroduction of FOLFOXIRI Plus Bevacizumab at progression versus FOLFOX Plus Bevacizumab followed by FOLFIRI Plus Bevacizumab at progression in first- and second-line treatment of unresectable metastatic colorectal cancer. The tribe-2 phase III study	F. De Braud	2015		III	35	17	Closed accrual
INT 0037/14	Use of donors with encephalic lesions and positive for hepatitis B surface antigen or hepatitis B core antibodies or anti-HCV antibodies according to national guidelines: improvement of organ sharing policies through a collection and analysis of organs' and patients' survival results in the short, medium and long term period - transplant research program according to the provisions of the Regional Committee Resolution n IX/1301 dated 9.02.2011	V. Mazzaferro	2014	01/01/2017	Observational	34	Closed accrual	
INT 0026/15	Follow-up to the AVANT study up to 8 and 10 years (median follow-up) in patients with colon carcinoma	R. Buzzoni	2015		Observational	34		
INT 0112/14	An open-label, randomized, multicenter, phase II trial designed to compare the efficacy of CAPTEM combination versus FOLFIRI as second line treatment in patients who have progressed on or after first-line Oxaliplatin-containing chemotherapy for advanced, MGMT methylated, RAS mutated colorectal cancer	F. De Braud	2014		II	33	12	4
INT 0007/13	A Phase III, Randomized, Double-Blind Study of Tivantinib (ARQ 197) in Subjects with MET Diagnostic-High Inoperable Hepatocellular Carcinoma (HCC) Treated with One Prior Systemic Therapy	V. Mazzaferro	2013	10/01/2017	III	28		
INT 0041/16	Observational study to validate a diagnostic multigene panel test for Hereditary Colorectal Cancer (TERC)	M. Vitellaro	2016		Observational	27	27	0

ONGOING CLINICAL STUDIES 2016-2017

GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0059/15	Randomized, multi-center, open-label trial of Pembrolizumab (MK-3475) versus Paclitaxel in subjects with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma who have progressed after failure of any combination chemotherapy containing a platinum and a fluoropyrimidine agent	M. Di Bartolomeo	2015		III	27	Closed accrual	
INT 0060/15	A Randomized, Double-Blind, Placebo-Controlled Phase III Study of Capecitabine and Cisplatin With or Without Ramucirumab as First-line Therapy in Patients With Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (RAINFALL)	M. Di Bartolomeo	2015		III	24	Closed accrual	
INT 0022/12	A randomized, double-blind, multicenter, Phase III study of Everolimus (RAD001) plus best supportive care versus placebo plus best supportive care in the treatment of patients with advanced NET of GI or lung origin - RADIANT-4	R. Buzzoni	2011		III	23		
INT 0183/15	A Randomized, Multi-center Phase III Study of Nivolumab versus Sorafenib as First-Line Treatment in Patients with Advanced Hepatocellular Carcinoma	V. Mazzaferro	2016		III	23	20	Closed accrual
INT 0184/13	Colorectal Cancer Control: Embracing the complexity, going back to basics	M. Gariboldi	2014		Observational	22	7	7
INT 0045/14	Activity and safety of Everolimus in combination with Octreotide LAR and Metformin in patients with advanced pancreatic well-differentiated Neuroendocrine Tumors (pWDNETs): a Phase II, open, monocentric, prospective study	F. De Braud	2014		II	22	5	2
INT 0180/15	Safety of Lanreotide 120 mg ATG in combination with Metformin in patients with progressive advanced Well-differentiated gastro-intestinal (GI) or lung carcinoids	S. Pusceddu	2016		II	18	10	8
INT 0156/15	Accuracy of endoscopic resection of 5-20 mm non-polypoid lesions with and without Narrow-Band Imaging (NBI): a multicenter prospective study	E. Masci	2015		Observational	17	15	1
INT 0023/17	A Phase II, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants with Advanced Gastric Cancer	M. Di Bartolomeo	2017		II	16		16



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GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0116/13	A prospective randomized clinical trial on 90Yttrium trans-arterial radio-Embolization (TheraSphere®) vs. Standard of care (Sorafenib) for the treatment of advanced Hepatocellular Carcinoma (HCC) with Portal Vein Thrombosis (PVT)	V. Mazzaferro	2014	02/05/2017	III	16	Closed accrual	
INT 0129/12	A randomized phase III study of low-dose docetaxel Oxaliplatin, Capecitabine (low-tox) vs Epirubicin, Oxaliplatin and Capecitabine (EOX) in patients with locally advanced unresectable or metastatic gastric cancer	M. Di Bartolomeo	2014		III	15	2	0
INT 0187/14	A multi-centre randomized clinical trial of biomarker-driven maintenance treatment for first-line metastatic colorectal cancer (MODUL)	M. Di Bartolomeo	2015		II	14	4	5
INT 0106/15	A Phase I/II Study of ARQ 087 in Adult Subjects with Advanced Solid Tumors with FGFR Genetic Alterations, Including Intrahepatic Cholangiocarcinoma with FGFR2 Gene Fusion	V. Mazzaferro	2015		I/II	14	12	Closed accrual
INT 0035/13	Prospective randomized phase II trial comparing mandatory second-look surgery with hyperthermic intraperitoneal chemotherapy (HIPEC) and cytoreductive surgery, vs. standard postoperative follow-up in patients at high risk of developing colorectal cancer peritoneal metastases	D. Baratti	2013		-	12	3	0
INT 0054/15	A Phase III, Randomised, Double Blind, Placebo Controlled, Multicentre Study of Maintenance Olaparib Monotherapy in Patients with gBRCA Mutated Metastatic Pancreatic Cancer whose Disease Has Not Progressed on First Line Platinum Based Chemotherapy	L. Celio	2015		III	12	5	5
INT 0103/16	"Assessment of Ramucirumab plus paclitaxel as switch MANtelnance versus continuation of first-line chemotherapy in patients with advanced HER-2 negative gastric or gastroesophageal junction cancers: the ARMANI phase III Trial"	M. Di Bartolomeo	2017		III	12		12
INT 0115/16	"A Phase III, open-label, multicenter, three-arm, randomized study to investigate the efficacy and safety of Cobimetinib plus Atezolizumab and Atezolizumab monotherapy vs. Regorafenib in patients with previously treated unresectable locally advanced or metastatic colorectal adenocarcinoma"	M. Di Bartolomeo	2016		III	12	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0062/17	The role of circulating gene transcripts to evaluate response to locoregional and surgical treatment for neuroendocrine	V. Mazzaferro	2017		Observational	11		11
INT 0198/14	Identification and characterization of circulating DNA in the blood of patients with advanced colorectal cancer and assessment of its changes during treatment with Cetuximab or Panitumumab, associated or not with chemotherapy	F. De Braud	2015		Observational	11		
INT 0082/14	BIOGIST Study: genomic analysis in gastrointestinal stromal tumors (GIST)	P. G. Casali	2014		Observational	10	0	0
INT 0141/16	A Phase I Study to Assess the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of BLU-554 in Patients with Hepatocellular Carcinoma	V. Mazzaferro	2017		I	9		9
INT 0122/13	A Phase II study on Trabectedin in advanced retroperitoneal leiomyosarcoma and well differentiated/dedifferentiated liposarcoma - TRAVELL Study	P. G. Casali	2014		II	9	1	3
INT 0053/16	The PANDA study: randomized phase II study of first-line FOLFOX plus Panitumumab versus 5FU plus Panitumumab in RAS and BRAF wildtype metastatic colorectal cancer elderly patients	F. De Braud	2016		II	9	3	6
INT 0017/04	A phase II, open label study of PTK787/ZK222584 in the treatment of metastatic Gastrointestinal Stromal Tumors (GISTS) resistant to Imatinib Mesylate	P. G. Casali	2004		II	9		
INT 0144/16	An open-label early access phase IIIb study of Trifluridine/Tipiracil (S95005/TAS-102) in patients with a pretreated metastatic colorectal cancer	M. Di Bartolomeo	2016		III	9	8	Closed accrual
INT 0176/14	Probe-based Confocal Laser Endomicroscopy (pCLE) in the clinical management of ampullary lesion of patients with Familial Adenomatous Polyposis	E. Masci	2015		Observational	8	0	1
INT 0079/13	A multicenter, stratified, open, randomized, comparator-controlled, parallel group phase III study comparing treatment with 177Lu-DOTAO-Tyr3-Octreotate to Octreotide LAR in patients with inoperable, progressive, somatostatin receptor positive midgut carcinoid tumours	E. Seregni	2013	31/12/2017	III	7	Closed accrual	



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GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0104/14	Evaluation of diagnostic accuracy of Diffusion Weighted MRI and Dynamic Contrast Enhanced MRI in mesorectal lymph node staging of rectal carcinoma	D. Scaramuzza	2017		Observational	6		6
INT 0154/15	Laser Endomicroscopy Of PAncReatic asymptomatic cyst Disease. Diagnostic accuracy of confocal endomicroscopy in indeterminate pancreatic cysts	E. Masci	2015		Observational	6	5	0
INT 0082/17	Randomized Phase III Study of Nivolumab plus Ipilimumab or Nivolumab Combined with Fluorouracil plus Cisplatin versus Fluorouracil plus Cisplatin in Subjects with Unresectable Advanced, Recurrent or Metastatic Previously Untreated Esophageal Squamous Cell Carcinoma	M. Di Bartolomeo	2017		III	6		6
INT 0002/15	A Single-Arm Phase II Study of Tivantinib (ARQ 197) plus Cetuximab in EGFR inhibitor-Resistant MET High Subjects with Locally Advanced or Metastatic Colorectal Cancer with Wild-Type KRAS	F. De Braud	2015	20/07/2017	II	6		
INT 0007/17	An open label phase II study to evaluate the efficacy and safety of PDR001 in patients with advanced or metastatic non-functional neuroendocrine tumors of pancreatic, gastrointestinal (GI), or thoracic origin who have progressed on prior treatment	S. Pusceddu	2017		II	5		Closed accrual
INT 0030/16	A Multicenter, Randomized, Open-label Study in Patients with esophageal Cancer refractory or intolerant to Combination Therapy with Fluoropyrimidine and Platinum-based Drugs	M. Di Bartolomeo	2016		III	5	4	Closed accrual
INT 0186/16	Early Nutrition Support in patients with oesophageal cancer undergoing chemo-radiotherapy	C. Gavazzi	2016		Observational	3	1	2
INT 0168/14	A phase Ib/II multi-center, open label, dose escalation study of WNT974, LGX818 and Cetuximab in patients with BRAFV600-mutant KRAS wild-type metastatic colorectal cancer harboring Wnt pathway mutations	F. De Braud	2015	16/01/2017	I/II	3		Closed accrual
INT 0141/15	"Efficacy and safety of lanreotide Autogel® 120 mg administered every 14 days in well differentiated, metastatic or locally advanced, unresectable pancreatic or midgut neuroendocrine tumours having progressed radiologically while previously treated with lanreotide Autogel® 120 mg administered every 28 days"	R. Buzzoni	2016		II	3	3	0

ONGOING CLINICAL STUDIES 2016-2017

GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0146/16	A randomized phase II trial of Captem or Folfiri as SEcond-line therapy in NEuroendocrine CArcinomas and exploratory analysis of predictive role of PET imaging and biological markers (SENECA study)	S. Pusceddu	2017		II	3		3
INT 0143/17	A Phase III, Randomized, Double-Blind, Clinical Trial of Pembrolizumab (MK-3475) plus Chemotherapy (XP or FP) versus Placebo plus Chemotherapy (XP or FP) as Neoadjuvant/Adjuvant Treatment for Subjects with Gastric and Gastroesophageal Junction (GEJ) Adenocarcinoma (KEYNOTE-585)	M. Di Bartolomeo	2017		III	2		2
INT 0123/14	Activation of the druggable pathways in gastric carcinomas and clinical outcomes of metastatic patients treated with Trastuzumab	M. Di Bartolomeo	2014	31/12/2017	Observational	2	0	Closed accrual
INT 0192/14	Optimized Response Assessment of Gastrointestinal Stromal Tumors Using Dual-Energy CT: Prospective Multicenter-Multinational Trial in Patients Undergoing Targeted Therapy with a TKI Inhibitor	P. G. Casali	2015		-	1	0	0
INT 0155/15	Probe-based Confocal Laser Endomicroscopy (pCLE) in the clinical management of duodenal polyps in patients with Familial Adenomatous Polyposis	E. Masci	2016		Observational	1	1	0
INT 0088/16	A Randomized, Multicenter, Double Blind, Phase III Study of Adjuvant Nivolumab or Placebo in Subjects with Resected Esophageal, or Gastroesophageal Junction Cancer	M. Di Bartolomeo	2017		III	1		1
INT 0110/16	A Study of Safety, Tolerability, and Clinical Activity of MEDI4736 and Tremelimumab Administered as Monotherapy and in Combination to Subjects with Unresectable Hepatocellular Carcinoma	F. De Braud	2017		I	1		1
INT 0064/17	Randomized phase III study of triplet mFOLFOXIRI plus Panitumumab versus mFOLFOX6 plus Panitumumab as initial therapy for unresectable RAS and BRAF wild-type metastatic colorectal cancer patients	F. De Braud	2017		III	1		1
INT 0032/16	"A Phase III Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of GS-5745 Combined with mFOLFOX6 as First Line Treatment in Patients with Advanced Gastric or Gastroesophageal Junction Adenocarcinoma"	M. Di Bartolomeo	2016		III	1	1	Closed accrual



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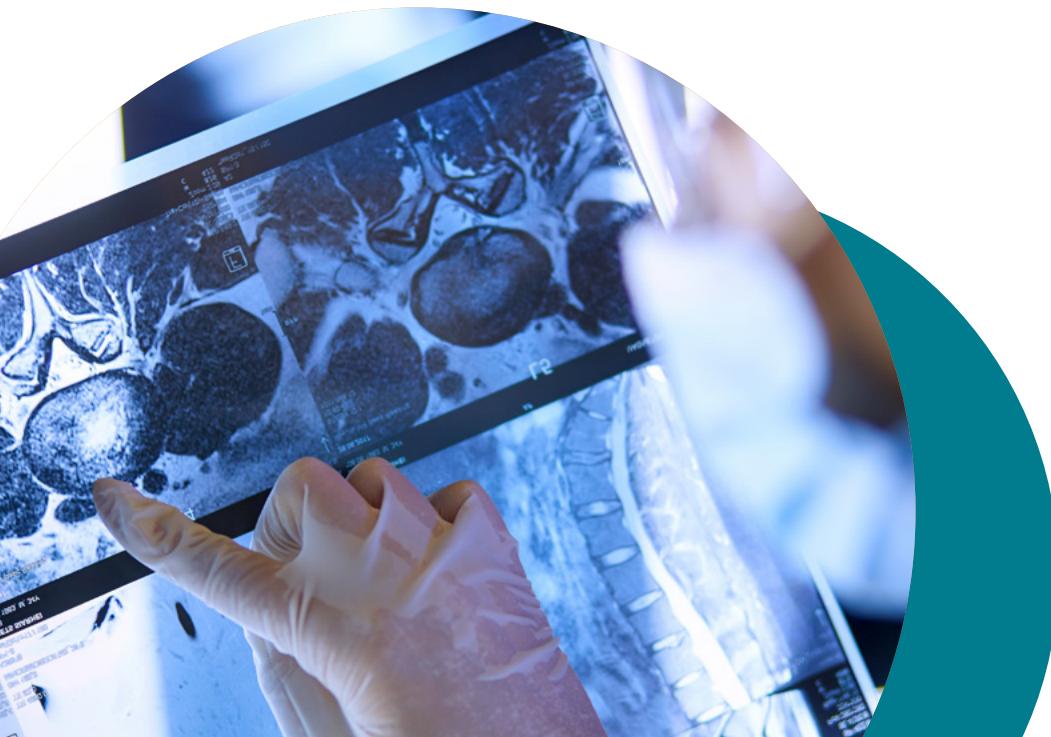
GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0050/16	A Phase III open-label,multicenter trial of maintenance therapy with Avelumab (MSB0010718C) versus continuation of first-line chemotherapy in subjects with unresectable, locally advanced or metastatic, adenocarcinoma of the stomach, or of the gastro-esophageal junction	M. Di Bartolomeo	2017		III	1		Closed accrual
INT 0080/10	A randomized, double-blind, placebo-controlled phase III of Regorafenib plus best supportive care versus placebo plus best supportive care for subjects with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) whose disease has progressed despite prior treatment with at least Imatinib and Sunitinib	P. G. Casali	2011	18/11/2016	III	10		
INT 0015/12	Pseudomixoma peritonei: prognostic analysis of micro-RNA and other factors using tissue	M. Deraco	2012	31/12/2016	Observational	63		
INT 0016/12	Multicenter Italian study on the CEUS assessment of Response of colorectal cancer metastasis Treated with Avastin (MIRTA)	R. Lanocita	2012	31/12/2016	IV	2		
INT 0077/12	A Non-Interventional Follow-Up to the VELOUR study (multicentre international study of afilbercept versus placebo in combination with FOLFIRI for metastatic colorectal cancer) – Translational Research	M. Di Bartolomeo	2013	01/03/2016	Observational	13		
INT 0159/13	DNA-seq analysis for prediction of outcome to first line Irinotecan versus Oxaliplatin-based regimens in advanced colorectal cancer patients enrolled in a randomized phase II, prospective study	M. Gariboldi	2013	31/12/2016	Observational	43		
INT 0002/14	A multicenter, phase II, single arm, two cohort study evaluating the efficacy, safety, and pharmacokinetics of AMG 337 in subjects with MET amplified gastric/gastroesophageal junction/esophageal adenocarcinoma or other MET amplified solid tumors	M. Di Bartolomeo	2014	14/03/2016	II	37		
INT 0050/14	The role of early systematic best palliative care versus on request palliative care consultation during standard oncologic treatment for patients with advanced gastric or pancreatic cancers: a randomized, controlled, multicenter trial	A. T. Caraceni	2014	24/11/2016	-	4	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

GASTROINTESTINAL CANCERS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0102/14	Observational study on perioperative management with COI regimen (Capecitabine plus Oxaliplatin and Irinotecan) in patients with gastric or gastroesophageal locally advanced and technically resectable cancer	M. Di Bartolomeo	2014	31/12/2016	Observational	12	Closed accrual	
INT 0107/14	Metabolomic profiling and colorectal cancer risk in the European Prospective Investigation into Cancer and Nutrition (EPIC) study	V. Krogh	2014	30/06/2016	Observational	175	Closed accrual	
INT 0164/14	Blood concentrations of persistent organic pollutants and pancreatic cancer risk within the European Prospective Investigation into Cancer and Nutrition (EPIC) cohort	V. Krogh	2015	31/12/2016	Observational	37	Closed accrual	
INT 0063/16	Molecular Analysis of Oncogenes in Tumor Samples from Adult Patients with Intrahepatic Cholangiocarcinoma or Mixed Hepatocellular-Cholangiocarcinoma	V. Mazzaferro	2016	30/11/2016	Observational	23	Closed accrual	
INT 0156/16	Modeling cancer specific prognosis in liver transplantation for hepatocellular carcinoma (HCC) with pre-transplant radiology assessment and alpha-fetoprotein	V. Mazzaferro	2016	28/10/2016	Observational	350	Closed accrual	
INT 0158/16	Sacral resection for pelvic recurrence of rectal carcinoma	F. Belli	2016	10/12/2016	Observational	10	Closed accrual	
INT 0051/15	Italian Registry of minimally invasive liver resections within the IGoMILS Association (Italian Group of Minimally Invasive Liver Surgery)	V. Mazzaferro	2015		-	81	33	28





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Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0046/07	Prostate cancer research international: active surveillance (PRIAS)	R. Valdagni	2007		Observational	627	70	77
INT 0054/07	Identification of Men with a genetic predisposition to ProstAte Cancer: Target Screening in BRCA1/2 mutation carriers and controls - the IMPACTstudy	N. Nicolai	2008		Observational	30	1	0
INT 0010/09	Carboplatin and Paclitaxel administered every three weeks vs Carboplatin and Paclitaxel administered weekly to patients with ovary carcinoma: multicentric randomized study	F. Raspagliesi	2009		III	39		
INT 0065/09	LION - Lymphadenectomy in ovarian neoplasm. An open randomized prospective multicenter trial. A project of the AGO Study Grop	F. Raspagliesi	2009	31/12/2017	-	32		
INT 0050/10	Multicentric observational study DUE-O1: urinary and erectile dysfunction after radical external beam therapy in localized prostate cancer	S. Villa	2010		Observational	174		
INT 0038/10	Tandem transplantation of autologous hematopoietic progenitors in relapsed/refractory patients with metastatic germinal tumors	R. Salvioni	2010		II	62	0	0
INT 0011/11	Breathing analysis by electronic nose for detection of ovarian cancer in general population and in population at risk	F. Raspagliesi	2011		Observational	306	35	50
INT 0106/11	A randomized phase II study of Carboplatin and Paclitaxel +/- Cetuximab, in advanced and/or recurrent cervical cancer	F. Raspagliesi	2012		II	13		
INT 0105/11	A randomized controlled study on the effectiveness of first-line chemotherapy (Carboplatin and Paclitaxel) versus chemo-immunotherapy (Carboplatin-Paclitaxel-Oregovomab) in patients with advanced epithelial ovarian, adnexal or peritoneal carcinoma	F. Raspagliesi	2012		II	11		
INT 0061/11	Randomized multicentric study comparing the efficacy of additional cytoreductive surgery vs exclusive chemotherapy in patients with platinum-sensitive recurrent ovarian cancer	F. Raspagliesi	2012		IV	7		
INT 0003/11	A phase III, randomized, double-blind trial of weekly paclitaxel plus AMG386 or placebo in women with recurrent partially platinum sensitive or resistant epithelial ovarian, primary peritoneal or fallopian tube cancers	F. Raspagliesi	2011	25/11/2016	III	12		

ONGOING CLINICAL STUDIES 2016-2017

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Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0095/11	Active surveillance "SA INT" in prostate cancer patients with low progression risk	R. Valdagni	2011		Observational	208	101	8
INT 0068/12	Rare tumors in gynecologic oncology: retrospective and prospective collection data on diagnosis and treatment of rare gynecologic neoplasia	D. Lorusso	2012		Observational	390	0	0
INT 0126/12	A multicenter study in patients with stage III-IV epithelial ovarian cancer treated with Carboplatin/Paclitaxel with Bevacizumab: clinical and biological prognostic factors	D. Lorusso	2013		IV	60		
INT 0018/12	A randomized phase II trial of Carboplatin-Paclitaxel compared to Carboplatin-Paclitaxel-Bevacizumab in advanced (stage III-IV) or recurrent endometrial cancer	F. Raspagliesi	2012		II	26		
INT 0020/12	Phase II study of Trabectedin (Yondelis) in BRCA1 e BRCA2 mutation carrier and BRCA ness phenotype advanced ovarian cancer patients	F. Raspagliesi	2012	27/11/2017	II	18		
INT 0002/12	A phase III randomized, double-blind, placebo-controlled, multi-center study of AMG 386 with Paclitaxel and Carboplatin as first-line treatment of subjects with FIGO stage III-IV epithelial ovarian, primary peritoneal or fallopian tube cancers	F. Raspagliesi	2012	19/06/2017	III	11		
INT 0123/12	Phase II study of single-agent Pazopanib (Votrient®) for patients with relapsed or refractory germ-cell tumors (GCT)	A. Necchi	2013	30/01/2017	II	43	Closed accrual	
INT 0110/12	Phase II study of the Pan-HER inhibitor Dacomitinib (PF-00299804) for patients with locally advanced or metastatic squamous cell carcinoma of the penis	A. Necchi	2013		II	32	15	1
INT 0074/13	A multicenter phase II randomized study with second line chemotherapy plus or minus Bevacizumab in patients with platinum sensitive epithelial ovarian cancer recurrence after a Bevacizumab/chemotherapy first line	D. Lorusso	2014		III	61	Closed accrual	
INT 0082/13	A double-blind, placebo-controlled, randomized, phase II study to evaluate the efficacy and safety of maintenance therapy with PankoMab-GEX™ after chemotherapy in patients with recurrent epithelial ovarian carcinoma	F. Raspagliesi	2013	28/07/2017	II	42	Closed accrual	



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Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0140/13	A phase III randomized double-blind trial of maintenance with Niraparib versus placebo in patients with platinum sensitive ovarian cancer	D. Lorusso	2014		III	20		
INT 0125/13	A phase III, randomised, double blind, placebo controlled, multicentre study of Olaparib maintenance monotherapy in patients with BRCA mutated advanced (FIGO Stage III-IV) ovarian cancer following first line platinum based chemotherapy	F. Raspagliesi	2014		III	11		
INT 0025/13	A phase III, randomized, double-blind trial of PEGylated Liposomal Doxorubicin (PLD) Plus AMG 386 or placebo in women with recurrent partially platinum sensitive or resistant epithelial ovarian, primary peritoneal, or fallopian tube cancer	F. Raspagliesi	2013	10/09/2016	III	14		
INT 0101/13	Pertuzumab in Platinum-resistant low HER3 mRNA epithelial ovarian cancer	D. Lorusso	2013	28/04/2016	III	11		
INT 0072/13	Predictive models of genito-urinary toxicity and erectile dysfunction after external high dose radiotherapy for prostate cancer	R. Valdagni	2015		-	24	6	7
INT 0033/13	External radiotherapy for intermediate or high risk prostate cancer: Irradiation of the pelvis and boost to the prostate in two 9 Gy fractions	S. Villa	2013		-	9	0	0
INT 0157/13	A randomized phase III, factorial design, of Cabazitaxel and pelvic radiotherapy in patients with localized prostate cancer and high-risk features of relapse	R. Valdagni	2014		III	1	0	0
INT 0030/13	Brentuximab Vedotin (SGN-35) as salvage therapy for males with advanced and platinum-resistant germ-cell tumors. An open label, single group, phase II trial	A. Necchi	2013	14/04/2016	II	9	Closed accrual	
INT 0128/13	RUAB2012-11: A retrospective study for the identification of predictive and prognostic biological factors in penile squamous cell carcinoma	A. Necchi	2014	31/12/2016	Observational	26	Closed accrual	
INT 0053/13	Non-invasive diagnosis of prostate cancer using urine samples – Feasibility study	C. Marenghi	2014	30/06/2016	Observational	36		
INT 0077/14	A multicentre study to examine the short and long term outcomes of the conservative management of benign-looking adnexal masses and the pre-operative characterisation of ovarian tumours	F. Raspagliesi	2014		Observational	330	85	Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

GENITAL APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0056/14	Disease recurrence in epithelial ovarian cancer: deciphering miRNA driven regulatory networks related to drug sensitivity/cellular plasticity and exploring nanomaterial-based targeted delivery of identified key molecules for therapeutic purposes	D. Mezzanzanica	2015	30/04/2017	Observational	100	57	Closed accrual
INT 0138/14	International Endometrial Tumor Analysis (IETA): an observational non-interventional academic multicentre study on the ultrasound features of the endometrium	F. Raspagliesi	2014	01/01/2017	Observational	50	16	Closed accrual
INT 0105/14	Chlamydia trachomatis and other infections and risk of ovarian cancer	V. Krogh	2014	01/08/2017	Observational	46		
INT 0012/14	A multicenter, randomized, double-blind, placebo-controlled phase III study of Rucaparib as switch maintenance following platinum-based chemotherapy in patients with platinum sensitive, high-grade serous or endometrial epithelial ovarian, primary peritoneal or fallopian tube cancer	D. Lorusso	2014		III	33		Closed accrual
INT 0073/14	Multicenter, randomized trial of Carboplatin +/- Paclitaxel in vulnerable elderly patients with stage III-IV advanced ovarian cancer	D. Lorusso	2015		II	11	8	0
INT 0010/14	The MILO study - MEK inhibitor in low-grade serous ovarian cancer: A multinational, randomized, open-label phase III study of MEK162 vs. physician's choice chemotherapy in patients with recurrent or persistent low-grade serous carcinomas of the ovary, fallopian tube or primary peritoneum	F. Raspagliesi	2015	01/04/2016	III	2		Closed accrual
INT 0016/14	What do primary and recurrent ovarian cancer (OC) patients expect from maintenance therapy? (EXPRESSION IV OVAR STUDY)	D. Lorusso	2014	31/03/2016	Observational	52		Closed accrual
INT 0108/14	Pilot Study of Metabolomic Profiles and Epithelial Ovarian Cancer Risk (1355GCC)	V. Krogh	2014	31/12/2016	Observational	50		Closed accrual
INT 0184/14	Project Plan Movember GAP3 Active Surveillance	R. Valdagni	2015		Observational	639	171	0
INT 0202/14	Modelling toxicity after high dose RT for prostate cancer: validating clinical, dosimetric and molecular factors	R. Valdagni	2016	31/05/2017	Observational	107	43	Closed accrual



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Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0032/14	A prospective, longitudinal, multinational, observational study to describe patterns of care and outcomes of men who are at high risk for poor clinical outcomes after experiencing biochemical failure following definitive prostate cancer therapy, men with castration-resistant prostate cancer and men with metastatic prostate cancer at initial diagnosis	G. Procopio	2014		Observational	75	Closed accrual	
INT 0208/14	Dissecting the role of microRNAs in the radiation response of human prostate cancer	N. Zaffaroni	2015	31/12/2017	Observational	50	5	Closed accrual
INT 0067/14	Observational study of gastrointestinal, haematologic and urinary toxicity induced by pelvis irradiation for prostate cancer	R. Valdagni	2014		Observational	30	11	6
INT 0186/14	A randomized, double-blind, placebo-controlled, phase IIIb study of the efficacy and safety of continuing Enzalutamide in chemotherapy naive metastatic castration resistant prostate cancer patients treated with Docetaxel plus Prednisolone who have progressed on Enzalutamide alone	G. Procopio	2015		III	26	Closed accrual	
INT 0161/14	Pros-IT CNR: Progetto per il monitoraggio dei Tumori della Prostata in Italia	R. Valdagni	2015		Observational	24		
INT 0193/14	REASSURE - Radium-223 alpha Emitter Agent in Safety Study in mCRPC popUlation for long-teRm Evaluation	R. Valdagni	2015		Observational	18	12	Closed accrual
INT 0005/14	A multinational, phase III, randomized, double-blind, placebo-controlled, efficacy and safety study of Enzalutamide in patients with nonmetastatic castration-resistant prostate cancer	G. Procopio	2014		III	15	4	Closed accrual
INT 0068/14	A phase III randomized, double-blind, placebo-controlled trial of radium-223 dichloride in combination with Abiraterone acetate and Prednisone/Prednisolone in the treatment of asymptomatic or mildly symptomatic chemotherapy-naive subjects with bone predominant metastatic castration-resistant prostate cancer (CRPC)	G. Procopio	2014		III	15	Closed accrual	
INT 0113/14	Phase II study of boost with ion beams followed by Image Guided / Intensity Modulated radiotherapy for high risk prostate cancer	R. Valdagni	2017		-	1		1
INT 0106/14	Serum amino acids and other metabolites in relation to prostate cancer risk in a case-control study nested within the EPIC study	V. Krogh	2014	28/02/2016	Observational	103	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

GENITAL APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0049/15	Correlation between genotype, phenotype and clinical outcome in BRCA mutated ovarian cancer: retrospective study	D. Lorusso	2015		Observational	86	14	0
INT 0197/15	Integrated genomic, epigenomic and metabolic approaches to overcome ovarian cancer early relapse and chemoresistance	D. Mezzanzanica	2016		Observational	60	60	0
INT 0181/15	Randomized phase III trial on Trabectedin (ET-743) vs clinician's choice chemotherapy in recurrent ovarian, primary peritoneal or fallopian tube cancers of BRCA mutated or BRCAness phenotype patients	D. Lorusso	2016		III	49	23	26
INT 0053/15	GYNADART Adaptive, MRI- guided brachytherapy in definitive treatment of locally advanced cervical carcinoma, according to the international recommendations: feasibility in daily practice, dosimetric and clinical outcome	A. Cerrotta	2015		Observational	40	15	Closed accrual
INT 0095/15	Phase III randomized clinical trial of Lurbinectedin (PM01183) versus Pegylated Liposomal Doxorubicin or Topotecan in patients with platinum-resistant ovarian cancer (CORAIL Trial)	D. Lorusso	2015		III	35	Closed accrual	
INT 0112/15	A randomized, double-blind, placebo-controlled, phase II study to assess the efficacy and safety of Farletuzumab (MORAb-003) in combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) in subjects with Low CA125 platinum-sensitive ovarian cancer	D. Lorusso	2016		II	11	3	8
INT 0077/15	A multicentre open-label single-arm phase II study evaluating the safety and efficacy of Bevacizumab in combination with Carboplatin and Paclitaxel in patients with metastatic, recurrent or persistent cervical cancer	D. Lorusso	2015		II	11	Closed accrual	
INT 0035/15	"A phase III, open label, randomised, controlled, multi-centre study to assess the efficacy and safety of Olaparib Monotherapy versus physician's choice single agent chemotherapy in the treatment of platinum sensitive relapsed ovarian cancer in patients carrying germline BRCA1/2 mutations"	F. Raspagliesi	2015		III	5	1	2



SCIENTIFIC REPORT 2016-2017

GENITAL APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0164/15	A randomized, open label, phase II trial of Bevacizumab plus weekly Paclitaxel followed by Bevacizumab monotherapy maintenance versus weekly Paclitaxel followed by observation in patients with relapsed ovarian sex-cord stromal tumours	D. Lorusso	2016		II	4	Closed accrual	
INT 0145/15	A prospective oBservational sTudy of patients with metastatic castration resistant prostate cancer progressing after stanDard hormonal therapy suitable for abiraterone acetate trEatment-ABlitude	G. Procopio	2016		Observational	40	23	Closed accrual
INT 0182/15	A phase III, randomized, open-label, controlled, multi-eenter, global study of first-line MEDI4736 monotherapy and MEDI4736 in combination with Tremelimumab versus standard of care chemotherapy in patients with unresectable stage IV urothelial cancer	A. Necchi	2016		III	29	Closed accrual	
INT 0048/15	Analysis of the prognostic value of body mass index in patients diagnosed with hormone refractory prostate cancer receiving chemotherapy: retrospective observational study	G. Procopio	2015	08/11/2017	Observational	28	0	Closed accrual
INT 0086/15	A phase II, two-arm multicenter, open-label study to determine the efficacy and the safety of two different dose regimens of a pan-FGFR Tyrosine Kinase inhibitor JNJ-42756493 in subjects with metastatic or surgically unresectable urothelial cancer with FGFR genomic alterations	A. Necchi	2015		II	10	6	3
INT 0036/15	A randomized, blinded, placebo-controlled, phase II trial of LEO011 in patients with relapsed, refractory, incurable teratoma with recent progression	A. Necchi	2015	07/04/2016	II	1		
INT 0118/15	"Characteristics of treatment and outcome of patients with locally advanced squamous cell carcinoma of the penis who had received perioperative systemic therapy"	A. Necchi	2016	31/12/2016	Observational	21	Closed accrual	
INT 0178/15	"A phase II study evaluating the efficacy of Enzalutamide and the role of ARv7 in metastatic castration resistant prostate cancer (mCRPC) patients with visceral disease"	E. Verzoni	2017		II	11		

ONGOING CLINICAL STUDIES 2016-2017

GENITAL APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0007/16	Randomized, double-blind, phase III trial of Olaparib vs. placebo in patients with advanced FIGO stage IIIB – IV high grade serous or endometrioid ovarian, Fallopian Tube, or Peritoneal Cancer treated with standard First-Line Treatment, Combining Platinum-Taxane Chemotherapy and Bevacizumab Concurrent with Chemotherapy and in Maintenance	D. Lorusso	2016		III	32	26	Closed accrual
INT 0119/16	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with HRD-Positive Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy	D. Lorusso	2017		III	23		23
INT 0118/16	A Phase II, Randomized Study of MLN0128 (a Dual TORC1/2 Inhibitor), MLN0128+MLN1117 (a PI3Ka Inhibitor), Weekly Paclitaxel, or the combination of Weekly Paclitaxel and MLN0128 in Women With Advanced, Recurrent, or Persistent Endometrial Cancer	F. Raspagliesi	2017		II	15		15
INT 0005/16	A Phase II, Open-label, Single-arm, Multicenter Study to Evaluate Efficacy and Safety of Pembrolizumab Monotherapy in Subjects with Advanced Recurrent Ovarian Cancer	F. Raspagliesi	2016		II	15	Closed accrual	
INT 0143/16	Phase II Study of Neoadjuvant Chemotherapy With Dose-Dense Paclitaxel In Association With Carboplatin followed by Radical Surgery for Locally Advanced Cervical Cancer (FIGO stage IB2- IIIA) Patients	D. Lorusso	2016		II	7	1	6
INT 0180/16	Phase III Multicenter, Randomized Study of Rucaparib versus Chemotherapy in Patients with Relapsed, BRCA-Mutant, High-Grade Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	D. Lorusso	2017		III	6		6
INT 0148/16	Randomized double-blind Phase II study comparing 3-weekly carboplatin (AUC 5) + paclitaxel 175 mg/m ² with or without concomitant and maintenance nintedanib (NINTEDANIB) in advanced or recurrent cervical carcinoma	D. Lorusso	2017		II	6		6
INT 0166/16	Phase II trial on trabectedin in the treatment of advanced uterine and ovarian carcinosarcoma (Cs) – MITO 26	D. Lorusso	2017		II	5		5

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Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0077/16	"Study of the role of BRCA1, BRCA2 and TP53 genes in the pathogenesis of gynecological carcinosarcomas in families with inherited predisposition to breast and ovarian cancer"	P. Radice	2016	31/12/2016	Observational	1854	Closed accrual	
INT 0099/16	Potential role of viral, bacterial and parasitic agents in the etiology of serous carcinoma of the female genitalia (endometrium, fallopian tube and ovary)	F. Raspagliesi	2016	31/12/2016	Observational	20	Closed accrual	
INT 0123/16	An open label, randomized, phase II study of the anti-Programmed Death-Ligand 1 (PD-L1) Durvalumab, alone or in combination with Tremelimumab, in patients with advanced and relapsed germ cell tumors	A. Necchi	2017		II	18		18
INT 0046/16	A randomized phase III trial comparing conventional-dose chemotherapy using paclitaxel, ifosfamide, and cisplatin (TIP) with high dose chemotherapy using mobilizing paclitaxel plus ifosfamide followed by High-dose carboplatin and etoposide (TI-CE) as first salvage treatment in relapsed or refractory germ cell tumours	A. Necchi	2016		III	12	1	11
INT 0191/16	"A Phase II, Open-Label, Single-Agent, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations"	A. Necchi	2017		II	5		5
INT 0060/16	Laparoscopic retroperitoneal lymph-node dissection in multimodal approach in germ-cell testicular tumours.	N. Nicolai	2016	30/09/2016	Observational	292	Closed accrual	
INT 0202/16	Prostate Cancer Outcomes Global Initiative to Compare and Reduce Variation in Localised Prostate Cancer ("PCO-CRV")	R. Valdagni	2017		Observational	156		156
INT 0205/16	Extracellular matrix and immune-infiltrate composition molds tumor growth and phenotype in prostate cancer	M. P. Colombo	2017		Observational	67		Closed accrual
INT 0059/16	Promoting engagement in healthy and active lifestyles among prostate cancer patients in active surveillance: a feasibility study	R. Valdagni	2017		-	24		24
INT 0113/16	Active Surveillance in early Prostate cancer following multiparametric magnetic Resonance imaging at Istituto Nazionale Tumori	N. Nicolai	2017		Observational	23		23

ONGOING CLINICAL STUDIES 2016-2017

GENITAL APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0108/16	Phase II Trial of Pembrolizumab (MK-3475) in Subjects with Metastatic Castration-Resistant Prostate Cancer (mCRPC) Previously Treated with Chemotherapy	G. Procopio	2016		II	4	Closed accrual	
INT 0049/16	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of JNJ-56021927 Plus Androgen Deprivation Therapy (ADT) Versus ADT in Subjects with Low-volume Metastatic Hormone-sensitive Prostate Cancer (mHSPC)	G. Procopio	2016		III	3	3	Closed accrual
INT 0154/16	Stromal gene signatures as source of targets for drug repositioning and prognostic biomarkers in prostate cancer	N. Zaffaroni	2017		Observational	2		2
INT 0074/16	"Dissecting the role of unexplored miR-205 host gene as long non-coding RNA in prostate basal cells: implications for cancer development"	P. Gandellini	2016	31/12/2016	Observational	98	Closed accrual	
INT 0009/17	Hysteroscopic vs. Cervical Injection for Sentinel Node Detection of Endometrial Cancer: a multicenter prospective randomized study	A. Ditto	2017		-	27		27
INT 0025/17	FORWARD 1: A Randomized, Open Label Phase III Study to Evaluate the Safety and Efficacy of Mirvetuximab soravtansine (IMGN853) Versus Investigator's Choice of Chemotherapy in Women with Folate Receptor a-positive Advanced Epithelial Ovarian Cancer, Primary Peritoneal Cancer or Fallopian Tube Cancer	D. Lorusso	2017		III	14		14
INT 0031/17	Prospective validation and comparison of subjective assessment, the International Ovarian Tumour Analysis (IOTA) ADNEX model, logistic regression model LR2, Simple Rules and the Risk of Malignancy Index (RMI) for discrimination between benign and malignant adnexal masses in the hands of ultrasound examiners with different levels of experience (IOTA7)	V. Chiappa	2017		Observational	5		5
INT 0033/17	A prospective observational trial on sentinel lymph node biopsy in patients with early stage cervical cancer	F. Raspagliesi	2017		Observational	3		3
INT 0117/17	Genitourinary BioBanking at the Vancouver Prostate Centre	A. Necchi	2017		Observational	24		24
INT 0098/17	Continuous spinal anesthesia for prostate brachytherapy: A retrospective study	F. Piccioni	2017		Observational	70		70
INT 0137/17	"Non invasive method of diagnosis of prostate cancer in urine samples"	R. Valdagni	2017		Observational	24		24



SCIENTIFIC REPORT 2016-2017

GENITAL APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0006/17	A Phase III, Open Label, Randomized Study to Assess the Efficacy and Safety of Olaparib (Lynparza™) Versus Enzalutamide or Abiraterone Acetate in Men with Metastatic Castration-Resistant Prostate Cancer Who have Failed Prior Treatment with a New Hormonal Agent and Have Homologous Recombination Repair Gene Mutation	G. Procopio	2017		III	3		3

HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0077/17	Head and Neck Squamous Cell Carcinoma bleeding: review	L. Licitria	2017	28/09/2017	Observational	259		Closed accrual
INT 0187/13	Identification of a molecular predictor of response to Cetuximab based on a phase II trial in recurrent/metastatic Head and Neck Squamous Cell Carcinoma (HNSCC)	S. Canevari	2014		Observational	200	Closed accrual	
INT 0178/13	Molecular Profile of metastatic sporadic medullary thyroid cancer (sMTC) patients and possible correlation with Vandetanib therapy	L. Locati	2014	31/12/2017	Observational	146	55	Closed accrual
INT 0037/17	Clinical and dosimetric prognostic factors research in a population of consecutive nasopharyngeal cancer patients treated with Intensity Modulated Radiation Therapy and chemotherapy, retrospective observational study	E. Orlandi	2017	31/12/2017	Observational	132		Closed accrual
INT 0065/16	A Prospective Observational Study for the Development and Validation of New Prognostic Models in Head and Neck Cancer Patients for Decision Support	L. Licitria	2017		Observational	128		128
INT 0203/16	Analysis of clinical outcomes of patients with recurrent-metastatic head and neck carcinoma, treated with chemotherapy + Cetuximab in first line: italian multicenter retrospective observational study	P. Bossi	2017		Observational	125		125
INT 0034/17	Outcome analysis of recurrent and metastatic head and neck squamous cell cancer patients after first line platinum and Cetuximab therapy	P. Bossi	2017	10/03/2017	Observational	117		Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0029/15	Quality of life and psychological functioning in patients with head and neck cancers treated with curative intent: an italian prospective multicenter study	E. Orlandi	2016		Observational	95	25	70
INT 0066/16	A Retrospective Observational Study for the Development and Validation of New Prognostic Models in Head and Neck Cancer Patients	L. Licitra	2017		Observational	79		79
INT 0055/14	Role of tumor microenvironment in thyroid carcinogenesis onset and progression: thyroid cells cross-talk with macrophage	A. Greco	2015		Observational	75	50	0
INT 0189/16	Identification of transcriptionally active HPV infection in formalin-fixed, paraffin-embedded biopsies of oropharyngeal carcinoma. Comparison between two in situ hybridization detection methods for HPV16 E6/E7 mRNA	A. Gloghini	2017	16/05/2017	Observational	70		Closed accrual
INT 0160/14	Prospective Observational Trial to Assess the Impact of Mucositis in patients treated with targeted therapy in Oncology	P. Bossi	2014	15/06/2017	Observational	64	Closed accrual	
INT 0060/17	Role of FDG PET-CT in patients with nasopharyngeal cancer treated with radiotherapy and chemotherapy: a retrospective study	A. Alessi	2017	30/09/2017	Observational	49		Closed accrual
INT 0106/16	A Phase I/II Dose Escalation and Cohort Expansion Study of the Safety, Tolerability and Efficacy of Anti-KIR (Lirilumab) Administered in Combination with Anti-PD-1 (Nivolumab) in Advanced Refractory Solid Tumors	L. Licitra	2016		I/II	45	22	23
INT 0070/17	Retrospective evaluation of translational and rotational patient set-up errors with a 6D robotic couch-top for image-guided brain and head and neck cancer radiotherapy	V. Mongioij	2016		Observational	44		44
INT 0092/14	Efficacy and safety of single agent pan-HER inhibitor Dacomitinib in the treatment of locally advanced unresectable or metastatic squamous cell cancer of the skin or with clinical contraindication to surgery	P. Bossi	2014		II	42	Closed accrual	
INT 0035/11	Cetuximab and Cisplatin with or without Paclitaxel in recurrent/metastatic head and neck cancer	L. Licitra	2012	20/06/2017	II	41	Closed accrual	



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HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0133/15	A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 Monotherapy and MEDI4736 in Combination with Tremelimumab Versus Standard of Care Therapy in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	L. Licitra	2015		III	36	22	Closed accrual
INT 0045/11	A single arm, open-label, phase II, multicentre study, to assess the safety of Vismodegib (GDC-0449) in patients with locally advanced or metastatic basal cell carcinoma	L. Licitra	2011	17/07/2017	II	34		
INT 0168/15	SUPREME-HN A Retrospective Cohort Study of PD-L1 in Recurrent and Metastatic Squamous Cell Carcinoma of Head and Neck	L. Licitra	2016	09/01/2017	Observational	32	32	Closed accrual
INT 0157/14	A randomized, double-blind, placebo controlled, mono-centre phase II study to evaluate the efficacy of treatment with ginseng in reducing fatigue in patients treated for head and neck cancer	P. Bossi	2015		-	30	7	18
INT 0038/15	Phase II study on Lenvatinib in recurrent and/or metastatic adenoid cystic carcinomas (ACC) of the salivary glands of the upper aerodigestive tract	L. Licitra	2015		II	27	9	Closed accrual
INT 0048/14	Health and economic outcomes of two different follow up strategies in effectively cured advanced head and neck cancer	L. Licitra	2014		-	24	2	6
INT 0135/14	Phase II study on Inlyta® (axitinib) in recurrent and/or metastatic salivary gland cancers (SGCs) of the upper aerodigestive tract	L. Licitra	2014		II	24	4	2
INT 0029/13	Multidisciplinary approach for poor prognosis sinonasal tumors: Phase II study of chemotherapy, photon and heavy ion radiotherapy integration for more effective and less toxic treatment in inoperable patients	L. Licitra	2013		II	23	7	6
INT 0156/14	A Phase III Randomized Trial of MK-3475 (Pembrolizumab) versus Standard Treatment in Subjects with Recurrent or Metastatic Head and Neck Cancer	L. Licitra	2015	15/04/2017	III	23		Closed accrual
INT 0061/14	An Open Label, Randomized Phase III Clinical Trial of Nivolumab vs Therapy of Investigator's Choice in Recurrent or Metastatic Platinum-refractory Squamous Cell Carcinoma of the Head and Neck (SCCHN)	L. Licitra	2014		III	23		

ONGOING CLINICAL STUDIES 2016-2017

HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0028/13	Multidisciplinary approach for poor prognosis sinonasal tumors: phase II study of chemotherapy, surgery, photon and heavy ion radiotherapy integration for more effective and less toxic treatment in operable patients	L. Licitra	2014		II	21	4	9
INT 0015/15	A randomized phase II study to evaluate the efficacy and safety of chemotherapy (CT) vs androgen deprivation therapy (ADT) in patients with recurrent and/or metastatic, androgen receptor (AR) expressing, salivary gland cancer (SGCs)	L. Locati	2015		II	17	13	2
INT 0137/14	A retrospective observational study on patients treated with concurrent Cetuximab and radiotherapy for locally advanced Squamous Cell Carcinoma of the Head&Neck	L. Licitra	2014		Observational	15	0	0
INT 0071/11	A multicentre, randomized, double-blind, placebo-controlled, phase III trial of E7080 in 13II-Refractory differentiated thyroid cancer (SELECT study)	L. Licitra	2012	17/05/2017	III	15		
INT 0035/12	An international, randomized, double-blind, two-arm study to evaluate the safety and efficacy of Vandetanib 150 and 300 mg/day in patients with unresectable locally advanced or metastatic medullary thyroid carcinoma with progressive or symptomatic disease	L. Licitra	2012	21/03/2017	IV	13		
INT 0157/16	Real-world efficacy and safety of Lenvatinib: data from the compassionate use in the treatment of RAI-Refractory Differentiated Thyroid Cancer in Italy	L. Locati	2017	15/11/2017	Observational	13		Closed accrual
INT 0199/14	HPV positive oropharyngeal cancer: characterization of immunological and viral profiles, and their role in the response to treatment	L. Locati	2015		Observational	12	3	3
INT 0091/11	Radioiodine therapy of differentiated thyroid carcinoma with maximized activity based on individualized dosimetry	E. Seregni	2012	31/12/2017	II	12	2	Closed accrual
INT 0069/13	Induction chemoThERapy followed by CEtuximab Plus definiTive radiOtheRapy versus radiation plus cisplatin	L. Licitra	2013		III	12	Closed accrual	
INT 0018/15	A randomized phase II study for tertiary prevention of squamocellular cancer of head and neck (SCCHN) with a dietary intervention	L. Licitra	2016		-	11	3	8
INT 0014/16	An Application for Head and Neck Cancer Patients: a Pilot Study	P. Bossi	2016		Observational	11	1	10



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HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0004/09	Phase II, multicenter, open-labe, 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	L. Licitra	2009	27/04/2017	II	11		
INT 0207/16	Dissection of thyroid tumor dependency on COPZ1 and MASTL activity: an approach to identify novel therapeutic targets	A. Greco	2017		Observational	10		10
INT 0095/13	A phase II study exploring the safety and efficacy of Nintedanib (BIBF1120) as second line therapy for patients with either differentiated or medullary thyroid cancer progressing after first line therapy	L. Licitra	2014		II	10	3	0
INT 0071/14	Phase II trial of Abiraterone Acetate in patients with relapsed and/or metastatic, castration resistant, salivary gland cancers	L. Licitra	2015		II	10	1	3
INT 0092/13	A Randomised, Double-Blind, Placebo-Controlled, Multi-Centre Phase III Study to Assess the Efficacy and Safety of Vandetanib (CAPRELSA™)300 mg in Patients with Papillary or Poorly Differentiated Thyroid Cancer That Is Either Locally Advanced or Metastatic Who Are Refractory or Unsuitable for Radioiodine (RAI) Therapy	L. Licitra	2013	07/02/2017	III	10		
INT 0159/16	A multicenter randomized trial to evaluate the efficacy of Fentanyl Pectin Nasal Spray (FPNS) versus Physician Choice (PC) - Usual Care (UC), in reducing incidental predictable breakthrough pain (IP-BTP) at swallowing in patients with head and neck cancer undergoing radiotherapy	P. Bossi	2017		IV	9		9
INT 0167/14	A phase II, multicenter, single arm study to assess the safety and efficacy of single agent CC-486 (oral Azacitidine) in previously treated subjects with locally advanced or metastatic nasopharyngeal carcinoma	L. Licitra	2015	06/04/2017	II	7		
INT 0031/16	A Phase Ib/II, Open-Label, Multicentre Study Assessing the Safety, Tolerability, Pharmacokinetics, and Preliminary Anti-tumor Activity of MEDI4736 inc ombination With AZD9150 or AZD5069 in Patients With Advanced Solid Malignancies and Subsequently Comparing AZD9150 and AZD5069 Both as Monotherapy and in Combination With MEDI4736 as Second Line Treatment in Patients With Recurrent and/or Metastatic Squamous Cell Carcinoma of the Head and Neck	L. Licitra	2016		I/II	6	2	4

ONGOING CLINICAL STUDIES 2016-2017

HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0191/15	A Phase III Clinical Trial of Pembrolizumab (MK-3475) in First Line Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma.	L. Licitra	2016		III	6	Closed accrual	
INT 0001/16	"A Phase III Randomized,Open-label, Multi-center, Global Study of MED14736 Alone or in Combination with Tremelimumab versus Standard of Care in the Treatment of First-line Recurrent or Metastatic Squamous Cell Head and Neck Cancer Patients"	L. Licitra	2016		III	6	5	Closed accrual
INT 0194/16	An Open Label, Randomized, Two Arm Phase III Study of Nivolumab in Combination with Ipilimumab versus Extreme Study Regimen (Cetuximab + Cisplatin/Carboplatin + Fluorouracil) as First Line Therapy in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	L. Licitra	2017		III	5		5
INT 0128/17	A Single-Arm, Open-Label, Multicenter, Phase IIb Clinical Trial with NIVolumab in Subjects with Recurrent or Metastatic Platinum-refRACTORY Squamous Cell Carcinoma of the Head and Neck (SCCHN)	L. Licitra	2017		III	5		5
INT 0160/16	Open-Label, Single-Arm, Multicenter, Phase II Trial of Lenvatinib for the Treatment of Anaplastic Thyroid Cancer (ATC)	L. Licitra	2017		II	4		4
INT 0046/17	Randomized, Double-blind Study To Evaluate the Efficacy and Safety of Cabozantinib (XL184) at 60 mg/Day Compared to 140 mg/Day in Progressive, Metastatic Medullary Thyroid Cancer Patients	L. Locati	2017		III	3		3
INT 0105/17	A phase II study of REGN2810, a fully human monoclonal antibody to programmed death-1, in patients with advanced basal cell carcinoma who experienced progression of disease on hedgehog pathway inhibitor therapy, or were intolerant of prior hedgehog pathway inhibitor therapy	L. Licitra	2017		II	2		2
INT 0034/16	A Phase Ib/III Multicenter, Randomized, Open-label Trial of Talimogene Laherparepvec in combination with Pembrolizumab for theTreatment of Subjects With Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	M. Di Nicola	2017		I/III	2		Closed accrual



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HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0159/17	Comprehensive geriatric assessment in tailored therapeutic choice for elderly head and neck cancer patients	P. Bossi	2017		-	1		1
INT 0140/16	A single arm, phase II, multicenter study to assess the efficacy and safety of Vismodegib and radiotherapy in patients with high risk or locally advanced basal cell carcinoma not amenable to radical surgery (VIRGILIO)	P. Bossi	2017		II	1		1
INT 0150/16	A Randomized Phase II trial of Neoadjuvant and Adjuvant Therapy with the IRX-2 Regimen in Patients with Newly Diagnosed Stage II, III or IVa Squamous Cell Carcinoma of the oral Cavity	L. Licitra	2017		II	1		1
INT 0037/06	A Phase III, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Weekly Doses of Palifermin (Recombinant Human Keratinocyte Growth Factor, rHuKGF) for the Reduction of Oral Mucositis in Subjects With Advanced Head and Neck Cancer Receiving Radiotherapy With Concurrent Chemotherapy (RT/CT)	L. Licitra	2007	22/09/2016	III	1		
INT 0005/09	An international, randomized, double-blinded, phase III efficacy study of XL184 versus placebo in subjects with unresectable, locally advanced, or metastatic medullary thyroid cancer	L. Licitra	2009	18/02/2016	III	9		
INT 0040/10	Phase II study of preoperative TPF chemotherapy in locally advanced resectable oral cavity squamous cell cancer in order to improve the rate of pathological complete response	L. Licitra	2011	29/08/2016	II	12	Closed accrual	
INT 0057/11	A randomised, double-blind, placebo-controlled, phase III study to evaluate the efficacy and safety of afatinib (BIBW 2992) as adjuvant therapy after chemo-radiotherapy in primary unresected patients with stage III, IVa, or IVb loco-regionally advanced head and neck squamous cell carcinoma	L. Licitra	2012	04/07/2016	III	3	Closed accrual	
INT 0076/12	Neoadjuvant afatinib based treatment strategies followed by surgery in squamous cell carcinoma of the head and neck: an EORTC NOCI-HNCG window study	L. Licitra	2012	28/04/2016	II	15		

ONGOING CLINICAL STUDIES 2016-2017

HEAD & NECK AND THYROID TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0121/13	Phase II multicenter randomized, double blind, placebo controlled study assessing the efficacy of Buparlisib (BKM120) Plus Paclitaxel vs. placebo Plus Paclitaxel in patients with platinum pre-treated recurrent or metastatic head and neck squamous cell carcinoma	L. Licitra	2013	23/11/2016	II	10		
INT 0052/14	Preventive treatment with MDD001 a medical device to reduce radiation induced dermatitis in head and neck cancer patients receiving curative treatment	E. Orlandi	2015	01/07/2016	-	41		
INT 0024/15	Development of an EORTC questionnaire for the assessment of quality of life in thyroid cancer patients (EORTC QLQ-THY)	L. Locati	2015	01/03/2016	Observational	25	Closed accrual	
INT 0172/15	Serum inflammation markers in relation to esophageal adenocarcinoma: a pooled analysis within the Cohort Consortium	V. Krogh	2015	30/12/2016	Observational	5	Closed accrual	

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0173/16	Long-term comorbidities among survivors of adult Hodgkin's lymphoma	S. Viviani	2016		Observational	338	82	256
INT 0074/17	Evaluation of lifestyle and eating habits changes among Multiple Myeloma patients after diagnosis	V. Montefusco	2017	24/11/2017	Observational	176		Closed accrual
INT 0125/16	Fear of cancer recurrence in adult survivors of hematological malignancies	C. Borreani	2016	10/10/2017	Observational	112	10	Closed accrual
INT 0044/08	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 (MM)	P. Corradini	2008		Observational	92	Closed accrual	
INT 0174/16	Observational study on the cognitive patterns and function in elderly patients survivors from Hodgkin or non Hodgkin lymphoma	C. Ripamonti	2016	01/06/2017	Observational	90	18	Closed accrual
INT 0095/17	Cognitive Survey on Perception of Protective Isolation and Quality of Life of Patients undergoing Hemopoietic Stem Cell Transplantation at the National Cancer Institute	G. Gobbi	2017	31/10/2017	Observational	71		Closed accrual



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HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0129/16	High resolution donor recipient HLA matching level in unrelated Hematopoietic Stem Cell Transplantation and impact on the transplant outcome: the Italian Experience	L. Farina	2016		Observational	59	59	0
INT 0055/17	Evaluation of biological samples from high-risk DLBCL patients receiving RDAEPOCH intensive chemotherapy	P. Corradini	2017		Observational	58		58
INT 0049/08	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	A. M. Gianni	2008	24/11/2017	II	52		
INT 0110/11	Cardiac biomarkers and innovative echocardiographic parameters as predictors of cardiotoxicity in B-cell non-Hodgkin/Hodgkin's lymphoma patients treated with anthracyclines or high-dose chemotherapy	P. Corradini	2012	31/12/2017	Observational	49	0	Closed accrual
INT 0138/12	A multicenter, single-arm, open-label study with Pomalidomide in combination with a low dose of Dexamethasone in subjects with refractory or relapsed and refractory multiple myeloma	P. Corradini	2013		III	47		
INT 0119/13	Prospective REsearch ASsessment in Multiple Myeloma: an OBservational Evaluation (PREAMBLE)	P. Corradini	2014		Observational	42	0	0
INT 0009/15	Prognostic role of GATA-3 and T-bet in peripheral T-cell lymphomas	P. Corradini	2015	30/06/2017	Observational	42	5	Closed accrual
INT 0055/16	Bone Marrow Derived Graft Composition and Survival Outcomes in the Setting of Allogeneic Hematopoietic Cell Transplant Using a Haploidentical Donor With High Dose Post-transplant Cyclophosphamide as Anti GVHD Prophylaxis	P. Corradini	2016	01/06/2017	Observational	42	18	Closed accrual
INT 0154/13	A multicenter, phase III, randomized study to evaluate the efficacy of a response-adapted strategy to define maintenance after standardchemoimmunotherapy in patients with advanced-stage Follicular Lymphoma	P. Corradini	2014		III	38	7	10
INT 0076/16	"Immunoscore for smoldering myeloma: impact of lymphocyte bone marrow infiltration and immunological inhibitory/costimulatory molecules on symptomatic disease development"	V. Montefusco	2016	30/05/2017	Observational	36	16	Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0128/16	"Monitoring disease response in B-cell malignancies using next generation sequencing of circulating plasma immunoglobulin heavy chain gene rearrangements"	P. Corradini	2016		Observational	34	12	22
INT 0200/16	"Retrospective assessment of serum soluble PDL1 levels in Hodgkin Lymphoma patients at diagnosis and during ABVD treatment"	A. Guidetti	2017		Observational	30		30
INT 0015/14	Whole exome sequencing of heavily pre-treated and Lenalidomide-Bortezomib refractory multiple myeloma patients	P. Corradini	2016	31/12/2017	Observational	30	24	Closed accrual
INT 0169/16	Retrospective analysis of mutational status of MYD 88 L265P in patients affected by Diffuse Large B cell Lymphoma treated up front with High dose Chemotherapy and ASCT	L. Devizzi	2017	30/06/2017	Observational	30		Closed accrual
INT 0048/07	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	P. Corradini	2007	03/03/2017	II	29	Closed accrual	
INT 0051/13	An observational prospective study on fertility and gonadal function in young adult female patients with lymphoma or sarcoma, who choose to undergo fertility preservation by mature oocytes cryopreservation before starting chemotherapy	S. Viviani	2013		Observational	27	9	Closed accrual
INT 0117/14	Observational study on the effectiveness of Brentuximab Vedotin (BV) in patients with Relapsed or Refractory Hodgkin Lymphoma (R/R HL) considered ineligible for a transplant procedure	S. Viviani	2014		Observational	26	0	0
INT 0089/11	A randomized phase III study to compare Bortezomib, Melphalan, Prednisone (VMP) with high dose Melphalan followed by Bortezomib, Lenalidomide, Dexamethasone (VRD) consolidation and Lenalidomide maintenance in patients with newly diagnosed multiple myeloma	P. Corradini	2012		III	25		
INT 0120/17	The Efficacy And Toxicity Of Donor Lymphocyte Infusions In The anagement Of Patients With Lymphoma Undergoing Allogeneic Stem Cell Transplantation	P. Corradini	2017	03/11/2017	Observational	24		Closed accrual



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HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0132/15	A multiarm, open label, randomized phase II study of MLN9708 plus oral Dexamethasone or plus oral Cyclophosphamide and Dexamethasone or plus Bendamustine and Dexamethasone or plus oral Thalidomide and Dexamethasone followed by maintenance with MLN9708 in newly diagnosed elderly multiple myeloma patients	P. Corradini	2015		II	23	6	15
INT 0075/17	Potential Benefit of Radiotherapy for Patients Undergoing Autologous Stem Cell Transplantation for Relapsed or Refractory Hodgkin's Lymphoma. (ASCT-RT)	A. Di Russo	2017		Observational	20		20
INT 0057/10	A phase III trial comparing Bortezomib, Cyclofosfamide and Dexamethasone versus Lenalidomide Cyclofosfamide and Dexamethasone in patients with multiple myeloma at first relapse	P. Corradini	2011	28/02/2017	III	20		
INT 0100/15	A retrospective study comparing allogeneic stem cell transplantation vs novel therapeutic agents in patients with high-risk chronic lymphocytic leukemia	L. Farina	2015	30/09/2017	Observational	20	0	Closed accrual
INT 0039/09	A 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	P. Corradini	2009		III	20		
INT 0040/15	A multicenter, randomized, open label phase II study of Carfilzomib, Cyclophosphamide and Dexamethasone (CCyd) as pre transplant induction and post transplant consolidation or Carfilzomib, Lenalidomide and Dexamethasone (CRd) as pre transplant induction and post transplant consolidation or continuous treatment with Carfilzomib, Lenalidomide and Dexamethasone (12 cycles) without transplant, all followed by maintenance with Lenalidomide (R) versus Lenalidomide and Carfilzomib (CR) in newly diagnosed Multiple Myeloma (MM) patients eligible for autologous transplant	P. Corradini	2015		II	17	9	Closed accrual
INT 0081/15	A non interventional observational retrospective post authorization study of relapsed and refractory Multiple Myeloma patients treated for at least 24 months with Lenalidomide and Dexametasone	V. Montefusco	2015		Observational	16	1	0

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0002/08	A phase III, multicentre, randomized, controlled study to determine the efficacy and safety of Lenalidomide, Melphalan and Prednisone (MPR) versus Melphalan (200 mg/m ²) followed by stem cell transplant in newly diagnosed multiple myeloma subjects	P. Corradini	2008		III	16		
INT 0009/09	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	S. Viviani	2009		III	16		
INT 0129/14	Phase III Study Comparing Daratumumab, Bortezomib and Dexamethasone (DvD) vs Bortezomib and Dexamethasone (Vd) in Subjects With Relapsed or Refractory Multiple Myeloma	P. Corradini	2015		III	16		
INT 0046/09	A phase III, multicentre, randomized, controlled study to determine the efficacy and safety of Ciclophosphamide, Lenalidomide and Dexamethasone (CRD) versus Melphalan (200 mg/m ²) followed by stem cell transplant in newly diagnosed multiple myeloma subjects	P. Corradini	2009		III	15		
INT 0033/11	A phase III, multicenter, open-label, randomized trial comparing the efficacy of GA 101 (RO50722759) in combination with CHOP (G-CHOP) versus Rituximab and CHOP (R-CHOP) in previously untreated patients with CD20-positive diffuse large B-cell lymphoma (DLBCL)	P. Corradini	2012		III	15		
INT 0150/14	Carfilzomib in combination with Bendamustine and Dexamethasone in refractory or relapsed multiple myeloma – A multicenter phase Ib/II trial of the European Myeloma Network Trialist Group (EMNTG)	P. Corradini	2015		I/II	15	13	Closed accrual
INT 0134/13	A Phase IB, Multi-center, Open-label Study of Novel Combinations of CC-122, CC-223, CC-292 and Rituximab in Diffuse Large B-cell Lymphoma	P. Corradini	2014		I	14	3	1
INT 0039/15	A phase III, randomized, double-blind study of PF-05280586 versus Rituximab for the first-line treatment of patients with CD20- positive, low tumor burden, follicular lymphoma	L. Devizzi	2015		III	14	10	Closed accrual
INT 0019/13	Study of the molecular mechanisms of chemo-resistance in peripheral T-cell Lymphomas (PTCLs) by massive-scale genome sequencing	P. Corradini	2016	31/12/2017	Observational	13	9	Closed accrual



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HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0187/16	The Outcome Of Patients With Follicular Lymphoma Relapsing After A Prior Autologous Stem Cell Transplant. A retrospective analysis from the LWP of the EBMT	P. Corradini	2017	31/12/2017	Observational	13		Closed accrual
INT 0014/06	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.	P. Corradini	2006		III	13		
INT 0031/13	A multicenter, open label study of weekly Carfilzomib, Cyclophosphamide and Dexamethasone (wCCy) in newly diagnosed Multiple Myeloma (MM) patients	P. Corradini	2013		I/II	13		
INT 0012/06	A phase II, multicenter study of Bortezomib, Pegylated Liposomal Doxorubicin, Dexamethasone (PAD) as induction and Melphalan 100 mg/m ² (MEL 100) as transplant, in elderly newly diagnosed multiple myeloma patients	P. Corradini	2006	01/01/2017	II	12		0
INT 0050/06	A phase II, multicenter study of Melphalan 100 mg/m ² (MEL 100) as transplant, Revlimid and Prednisone (RP) as consolidation and Revlimid alone as maintenance in elderly newly diagnosed multiple myeloma patients	P. Corradini	2006		II	12		
INT 0100/13	Multi-center, phase II study to assess the safety and efficacy of haploidentical bone marrow transplantation using reduced intensity conditioning (RIC) regimen and post-transplant Cyclophosphamide, in patients with poor prognosis lymphomas	P. Corradini	2013		II	12	3	Closed accrual
INT 0188/16	Clonal Evolution And drug Resistance in multiple MYELOMA: from patient biopsies to single cells to cell-free DNA and back	P. Corradini	2017		Observational	11		11
INT 0012/10	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	P. Corradini	2010	24/10/2017	I/II	11		
INT 0038/16	A retrospective study to evaluate the clinico-biologic characteristics and outcome of patients treated in Italy according to the Ibrutinib-Named Patient Program (NPP) for patients with relapsed or refractory chronic lymphocytic leukemia (CLL)	L. Farina	2016		Observational	10	10	0

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0056/16	Detection of Poor Mobilizer (PM) in Multiple Myeloma (MM) patients: prospective product registry	P. Corradini	2016		Observational	9	6	3
INT 0175/15	Phase II study on the role of Brentuximab Vedotin as single agent in the treatment of relapsed/refractory CD30 positive peripheral T cell lymphoma (PTCL) patients	P. Corradini	2016		II	9	7	2
INT 0083/13	A Randomized, Open-label, Phase III Trial of A+AVD Versus ABVD as Frontline Therapy in Patients With Advanced Classical Hodgkin Lymphoma	S. Viviani	2014		III	9		
INT 0149/14	Phase III randomized, double-blind, placebo controlled, multicenter study to compare the efficacy and safety of Lenalidomide (CC-5013) plus R-CHOP chemotherapy (R2-CHOP) versus placebo plus R-CHOP chemotherapy in subjects with previously untreated activated b-cell type diffuse large b-cell lymphoma	P. Corradini	2015		III	9	3	Closed accrual
INT 0087/14	Romidepsin in combination with Choep as first line treatment before hematopoietic stem cell transplantation in young patients with nodal peripheral T-cell lymphomas: a phase I-II study	P. Corradini	2014		I/II	8	0	1
INT 0138/15	A phase II study with Bendamustine Plus Brentuximab Vedotin in Hodgkin's lymphoma and CD30 + peripheral T-cell lymphoma in first salvage setting: the BBV regimen	P. Corradini	2015		II	8	7	0
INT 0147/14	"A phase III, multicentre, randomized, controlled study to determine the efficacy and safety of standard schedule versus a new algorithm of dose reductions in elderly and unfit newly diagnosed multiple myeloma patients receiving lenalidomide plus steroids"	P. Corradini	2015		III	8	1	Closed accrual
INT 0063/15	A phase I/II clinical trial to assess safety and efficacy of a new treatment for Hodgkin lymphoma's disease combining Adcetris® and Levact® in Old patients	S. Viviani	2015		I/II	7	2	2
INT 0096/15	Observational study of BVD regimen (Bendamustine, Velcade, Dexamethasone) after AIFA authorization (Law 648, 13/08/2014)	P. Corradini	2015		Observational	7	4	1
INT 0021/14	Ofatumumab-Bendamustine for relapsed/refractory indolent lymphoma: a multicenter phase 2 trial	P. Corradini	2014		II	7	2	0



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HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0011/13	Myeloablative Conditioning, followed by Unmanipulated Haploididential Bone Marrow Transplantation and post-transplant high dose Cyclophosphamide, for Patients with Hematologic Malignancies: a Phase II study	P. Corradini	2013	01/01/2017	II	7		
INT 0031/10	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)	S. Viviani	2010		III	7		
INT 0135/13	A single arm, multicentre, phase IIIb study to evaluate safety, efficacy and pharmacokinetic (PK) of subcutaneous (SC) Rituximab administered during induction phase or maintenance in previously untreated patients with CD20+ diffuse large B cell lymphoma (DLBCL) or follicular lymphoma (FL)	P. Corradini	2014		III	7		
INT 0174/15	"A Phase Ib multicenter, open-label study to determine the recommended dose and regimen of Durvalumab (MEDI4736) either as monotherapy or in combination with Pomalidomide (POM) with or without low dose-Dexamethasone (DEX) in subjects with relapsed and refractory multiple myeloma (RRMM)"	P. Corradini	2016		I/II	6	5	1
INT 0070/16	Evaluation of the immunomodulatory effects of therapy with Brentuximab	L. Rivoltini	2016		Observational	6	6	0
INT 0142/13	Phase IIa study on the role of Gemcitabine plus Romidepsin (GEMRO regimen) in the treatment of relapsed/refractory peripheral T-cell lymphoma patients	P. Corradini	2014		II	6		
INT 0033/16	An Open-Label Treatment Use Protocol for Daratumumab in Subjects with Multiple Myeloma Who Have Received at Least 3 Prior Lines of Therapy (Including a Proteasome Inhibitor and an Immunomodulatory Agent) or are Double Refractory to a Proteasome Inhibitor and an Immunomodulatory Agent	P. Corradini	2016	10/03/2017	III	6	Closed accrual	
INT 0066/12	A phase III multicenter, randomized study comparing consolidation with 90YTRIUM-LABELED IBRITUMOMAB TIUXETAN (ZEVALIN®) radioimmunotherapy vs autologous stem cell transplantation (ASCT) in patients with relapsed/refractory follicular lymphoma (FL) aged 18-65 years	P. Corradini	2013		III	5	0	0

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0162/15	An open label multicenter Phase Ib/II trial to determine the dose of BI 836826 in combination with gemcitabine and oxaliplatin (GemOx) and the efficacy of BI 836826-GemOx versus rituximab (R)- in combination with GemOx (R-GemOx) in patients with relapsed/ refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for, or have failed autologous stem cell transplant	P. Corradini	2016		I/II	5	4	1
INT 0047/13	Phase II randomized study with R-DHAP +/- Bortezomib as induction therapy in relapsed/refractory Diffuse Large B-cell Lymphoma (DLBCL) patients before High-Dose chemotherapy BEAM with autologous stem cell transplantation (ASCT): BR-DHAP + BEAM + ASCT versus R-DHAP + BEAM + ASCT.	P. Corradini	2014		II	5	0	0
INT 0192/15	Lenalidomide in pretreated Diffuse Large B-Cell Lymphoma patients: an Italian observational multicenter retrospective study in daily clinical practice	P. Corradini	2016	01/01/2017	Observational	5	5	Closed accrual
INT 0131/12	A randomized open-label multicenter phase II trial evaluating the safety and activity of DCDT2980S in combination with Rituximab or DCDS4501A in combination with Rituximab in patients with relapsed or refractory B-cell Non-Hodgkin's lymphoma	P. Corradini	2013		II	5		Closed accrual
INT 0097/14	Prospective data collection of elderly patients (>= 65 years) with Diffuse Large B-cell Lymphoma (DLBCL) receiving at the time of diagnosis Multidimensional Geriatric Assessment (VGM)	P. Corradini	2014		Observational	5	1	Closed accrual
INT 0002/05	A multicenter, open label study of oral Melphalan, and CC-5013 (Revlimid) (MPR) as induction therapy in elderly newly diagnosed multiple myeloma patients	P. Corradini	2005	12/02/2017	I/II	4		
INT 0094/17	A retrospective study to evaluate the activity of the interferon-free regimens during or after immune-chemotherapy in patients with hepatitis C virus-associated diffuse large B-cell lymphoma	L. Farina	2017	01/09/2017	Observational	4		Closed accrual
INT 0173/15	Pomalidomide combined with Carfilzomib and Dexamethasone (PCd) for induction and consolidation followed by Pomalidomide combined with Dexamethasone vs Pomalidomide maintenance for patients with Multiple Myeloma in progression after prior 1st line treatment with Lenalidomide and Bortezomib	P. Corradini	2016		II	4	3	1

**SCIENTIFIC REPORT 2016-2017****HEMATOLOGIC MALIGNANCIES**

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0048/10	Intensified program including bendamustine followed by PBSC mobilization and high dose therapy and autograft for patients with relapsed or resistant CD 20+ follicular Non Hodgkin Lymphoma: a multicenter, pivotal GITIL study	A. M. Gianni	2012	01/01/2017	II	4		
INT 0057/15	A Phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of Copanlisib in combination with Rituximab in patients with relapsed indolent B-cell non-Hodgkin's lymphoma (iNHL) - CHRONOS-3	L. Devizzi	2016		III	3	2	1
INT 0058/11	A phase III, Randomized, open label trial of Lenalidomide/Dexamethasone with or without Elotuzumab in relapsed or refractory multipl myeloma	P. Corradini	2012	01/01/2017	III	3		0
INT 0008/11	A multicenter phase II study of subcutaneous Velcade Plus Oral Melphalan and Prednisone or Plus oral Cyclophosphamide and Prednisone or Plus Prednisone in newly diagnosed elderly multiple myeloma patients	P. Corradini	2011	27/03/2017	II	3		
INT 0041/14	Risk-adapted, MRD-directed therapy for young adults with newly diagnosed acute myeloid leukemia	P. Corradini	2014	16/05/2017	II	3		
INT 0080/15	A Phase II Clinical Trial of MK-3475 (Pembrolizumab) in Subjects with Relapsed or Refractory (R/R) Classical Hodgkin Lymphoma (cHL)	P. Corradini	2015		II	3	Closed accrual	
INT 0001/17	A Phase III Randomized, Open-label, Multicenter Study Comparing Isatuximab (SAR650984) in Combination with Pomalidomide and Low-dose Dexamethasone versus Pomalidomide and Low-dose Dexamethasone in Patients with Refractory or Relapsed and Refractory Multiple Myeloma	P. Corradini	2017		III	3		Closed accrual
INT 0127/16	Whole genome sequencing of serial samples of a rare acute myeloid leukemia case	P. Corradini	2017	31/12/2017	Observational	2		Closed accrual
INT 0056/10	A randomized, open label study of Ofatumumab and Bendamustine combination therapy compared with Bendamustine monotherapy in indolent B-cell non-Hodgkin's lymphoma unresponsive to Rituximab or a Rituximab-containing regimen during or within six months of treatment	P. Corradini	2013		III	2	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0065/15	"MIRO" study (Molecularly Oriented Immuno-radio-therapy): a multicenter phase II trial for the treatment on molecular basis of stage I/II Follicular Lymphoma with local radiotherapy with/without Ofatumumab	P. Corradini	2017		II	2		2
INT 0175/16	A phase II trial addressing feasibility and activity of Clarithromycin + Lenalidomide combination: a full oral treatment for patients with relapsed/ refractory extranodal mucosa-associated lymphoid tissue (MALT) lymphoma (CLEO Study)	L. Devizzi	2017		II	2		2
INT 0037/11	A multicenter, open label phase II study of Carfilzomib, Cyclophosphamide and Dexamethasone in newly diagnosed multiple myeloma patients	P. Corradini	2011	15/11/2017	II	2		
INT 0063/13	An open label, single arm, phase II study of Nilotinib 300 mg BID in newly diagnosed CPCML patients, in order to verify disappearance of CD34+/lin-Ph+ cells from bone marrow during treatment	P. Corradini	2013	05/07/2017	II	2		
INT 0062/14	Single-Arm, Open-Label Phase II Study of Nivolumab (BMS-936558) in Subjects with Relapsed or Refractory Follicular Lymphoma (FL)	P. Corradini	2014	08/09/2017	II	2	Closed accrual	
INT 0063/14	"Single-Arm, Open-Label, Phase II Study of Nivolumab (BMS-936558) in Subjects with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL) After Failure of Autologous Stem Cell Transplant (ASCT) or After Failure of At Least Two Prior Multi-Agent Chemotherapy Regimens in Subjects Who Are Not Candidates for ASCT"	P. Corradini	2014	27/10/2017	II	2		
INT 0041/15	Prospective, phase II study to evaluate the efficacy and the safety of a combination of Bendamustine-Melphalan as preparative regimen to autologous transplantation of hematopoietic cells for multiple myeloma who have relapsed after previous high-dose therapy.	P. Corradini	2015		II	2	Closed accrual	
INT 0078/15	"A randomized phase III multicenter trial assessing efficacy and toxicity of a combination of Rituximab and Lenalidomide (R2) vs Rituximab alone as maintenance after chemoimmunotherapy with Rituximab-Bendamustine for relapsed/refractory FL patients not eligible for autologous transplantation (ASCT)"	P. Corradini	2015		III	1	0	0



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HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0083/16	A Phase III, Randomized, Open-label, Clinical Trial to Compare Pembrolizumab with Brentuximab Vedotin in Subjects with Relapsed or Refractory Classical Hodgkin Lymphoma	P. Corradini	2017		III	1		1
INT 0181/14	Post-Authorisation Safety Study (PASS) MA2510: An Observational Cohort Study of the Safety of Brentuximab Vedotin in the Treatment of Relapsed or Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma	P. Corradini	2016	29/12/2017	Observational	1	1	Closed accrual
INT 0119/15	Chronic myelogenous leukemia patients' risk attitude profile RISKY-CML - Study protocol	P. Corradini	2016	01/05/2017	Observational	1	1	Closed accrual
INT 0084/13	Eltrombopag in patients with delayed post transplant thrombocytopenia	P. Corradini	2016		II	1	1	0
INT 0003/16	"A multicenter study to evaluate the anti-viral activity of an interferonfree treatment with sofosbuvir plus ledipasvir ± ribavirin (G1, 3 and 4)and sofosbuvir + ribavirin (G2) for patients with hepatitis C virusassociated indolent B-cell lymphomas"	A. Dodero	2016		II	1	1	0
INT 0083/17	A Multi-Center, Open Label, Uncontrolled, Phase IIa Clinical Trial Evaluating the Safety and Efficacy of the Addition of Ibrutinib to Venetoclax through a MRDguided Approach in Relapsed/ Refractory Patients with Chronic Lymphocytic Leukemia (CLL)	L. Farina	2017		II	1		1
INT 0180/14	A pilot phase II study with Brentuximab Vedotin as pre-ASCT induction therapy in relapsed/refractory Hodgkin's lymphoma patients non responding to IGEV salvage treatment	P. Corradini	2015	14/06/2017	II	1	Closed accrual	
INT 0111/15	GA101-miniCHOP regimen for the treatment of elderly unfit patients with diffuse large B-cell non-Hodgkin's lymphoma. A phase II study of the Fondazione Italiana Linfomi (FIL)	P. Matteucci	2016	31/12/2017	II	1	1	Closed accrual
INT 0139/15	"A phase II, single arm, multicenter trial to determine the efficacy and safety of CTLO19 in adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL)"	P. Corradini	2016	11/12/2017	II	1	1	Closed accrual
INT 0013/09	Safety and efficacy of lenalidomide as main therapy in patients with newly diagnosed multiple myeloma following a tandem autologous-allogeneic transplant	P. Corradini	2009		II	1		

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0074/14	A phase II study of Chlorambucil in combination with subcutaneous Rituximab followed by maintenance therapy with subcutaneous Rituximab in patients with extranodal marginal zone B-cell lymphoma of mucosa associated lymphoid tissue (MALT LYMPHOMA)	L. Devizzi	2015		II	1	Closed accrual	
INT 0007/10	Monitoring of human polyomavirus reactivation in patients with lymphoproliferative disease treated with chemotherapy, chemotherapy and Rituximab, and Rituximab Alone	P. Corradini	2010	31/12/2016	Observational	8		
INT 0072/11	An open label non randomized phase II study evaluating SAR3419, an anti-CD19 antibody-maytansine conjugate administered as single agent by intravenous infusion to patients with relapsed or refractory D19+ diffuse large B cell lymphoma	A. Guidetti	2012	12/09/2016	II	3		
INT 0080/11	Prospective, phase I/II, non -randomized, open label, multicenter study to determine safety and efficacy of Nilotinib in a population with steroid-refractory/or steroid-dependent cGVHD	P. Corradini	2012	25/03/2016	I/II	2		
INT 0057/13	A phase I/II study of Danusertib in Combination with romidepsin in adult patients with mature peripheral T-Cell lymphoma (PTCL)	P. Corradini	2013	20/09/2016	I/II	7	Closed accrual	
INT 0086/13	Identification of possible genetic causes responsible of a familiar form of Multiple Myeloma	P. Corradini	2013	31/12/2016	Observational	4		
INT 0113/13	Role of T memory stem cell in the process of immune reconstitution following bone marrow transplantation	P. Corradini	2013	01/03/2016	Observational	17	Closed accrual	
INT 0036/14	A prospective, multicenter survey of Severe Infections by Gram Negative Bacteria in patients submitted to autologous and allogeneic stem cell transplant	P. Corradini	2014	05/04/2016	Observational	56		
INT 0095/14	Identification of biological/clinical prognostic factors in patients with not-transformed Hodgkin Lymphoma	P. Corradini	2014	31/12/2016	Observational	13	Closed accrual	
INT 0124/14	Prevalence study of eye disorders in patients with symptomatic multiple myeloma	V. Montefusco	2014	31/12/2016	Observational	110	Closed accrual	
INT 0159/14	The role of haploidentical hematopoietic stem cell transplantation in multiple myeloma	V. Montefusco	2015	31/12/2016	Observational	4	Closed accrual	



SCIENTIFIC REPORT 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0179/14	A Retrospective, Observational study on the prognostic role of the histological grade in patients with refractory or relapsed Follicular non Hodgkin Lymphoma undergoing Allogeneic Hematopoietic Stem Cell Transplantation	P. Corradini	2015	31/12/2016	Observational	2	Closed accrual	
INT 0044/15	Retrospective study of the prognostic value of MYC/BCL2 coexpression in relapsed/refractory Diffuse large B-cell lymphoma patients treated with autologous- and/or allogeneic-hematopoietic stem cell transplantation	P. Corradini	2015	30/06/2016	Observational	71	Closed accrual	
INT 0068/15	"Biomolecular characteristics of lymphoplasmacytic lymphoma without IgM monoclonal protein: a biological study of "Rete Ematologica Lombarda" clinical network"	P. Corradini	2016	03/03/2016	Observational	6	Closed accrual	
INT 0082/15	Quantification of the Time and Effort Required for Peripheral Blood Stem Cell Collection-The European Perspective	P. Corradini	2015	23/09/2016	Observational	46	Closed accrual	
INT 0170/15	Observational study on adherence to oral therapy in patients with onco-hematologic disease treated at Fondazione IRCCS Istituto Nazionale Tumori	L. Pancheri	2016	15/04/2016	Observational	80	Closed accrual	
INT 0186/15	An observational study to assess the efficacy and safety of Bendamustine Plus Rituximab in patients affected by chronic lymphocytic leukemia	L. Farina	2016	31/12/2016	Observational	20	Closed accrual	
INT 0016/16	Retrospective Observational Study on Mieloma Multiplo data downloaded from REL registry (Retrospective Observational Study)	V. Montefusco	2016	10/11/2016	Observational	197	Closed accrual	
INT 0078/16	An Italian multicenter retrospective observational study to assess the clinical characteristics and the outcome of patients with relapsed or refractory mantle cell non-Hodgkin's lymphoma treated in Italy according to the ibrutinib Named Patient Program (NPP)	F. Spina	2016	27/07/2016	Observational	5	Closed accrual	
INT 0100/16	"Outcome of reduced-intensity allogeneic transplant in Hodgkin's lymphoma: analysis of the impact on the long-term survival of the timing of relapse after autologous transplant and primary refractory disease"	P. Corradini	2016	31/12/2016	Observational	62	Closed accrual	
INT 0112/16	Allogeneic Stem Cell Transplantation and Subsequent Treatments as a Comprehensive Strategy for Long Term Survival of Multiple Myeloma Patients	P. Corradini	2016	20/12/2016	Observational	68	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

HEMATOLOGIC MALIGNANCIES

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0133/12	Chronic Lymphocytic Leukemia (CLL) Registry: a prospective, observational study within the Rete Ematologica Lombarda	P. Corradini	2013		-	53	5	3
INT 0058/13	"Chronic Myeloid Leukemia Register - Lombardia Hematology Network"	P. Corradini	2014		-	1	0	0

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0021/11	BioMILD: a prospective study of efficacy of plasma microRNA as first line test for early diagnosis of lung cancer	U. Pastorino	2013		Observational	4119	Closed accrual	
INT 0171/16	Observational Study on Prognostic and Predictive role of Immunocontexture and Microenvironment characterization in Non Small Cell Lung Carcinomas	M. Milione	2016		Observational	195	195	0
INT 0022/15	Observational study to assess the prognostic impact of factors related to the immune response in non-small cell lung cancer	M. Garassino	2015		Observational	143	28	56
INT 0023/16	Lung metastasectomy for sarcomas in pediatric patients: searching for factors that predict long-term survival	U. Pastorino	2016	18/01/2017	Observational	140	140	Closed accrual
INT 0089/14	Protective versus conventional ventilation during thoracic surgery	F. Piccioni	2014	05/07/2017	-	100	24	Closed accrual
INT 0018/13	K-RAS mutations and DNA Repair Function in NSCLC	M. Garassino	2014	24/06/2017	Observational	86	17	Closed accrual
INT 0146/15	PD-1 and PD-L1 in thymic neoplasm: a translational study	M. Garassino	2016		Observational	71	71	0
INT 0167/16	KISS1 and KISS1-related networks in drug resistance and metastasis in Non Small Cell Lung Cancer	P. Perego	2017		Observational	67		67
INT 0042/14	A phase II, multicenter, single-arm study of MPDL3280A in patients with PD-L1 positive locally advanced or metastatic non small cell lung cancer	M. Garassino	2014		II	66		



SCIENTIFIC REPORT 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0111/14	A Phase II, Non-comparative, Open label, Multi-centre, International Study of MEDI4736, in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (Stage IIIB-IV) who have received at least Two Prior Systemic Treatment Regimens Including One Platinum-based Chemotherapy Regimen (ATLANTIC)	M. Garassino	2014	15/12/2017	II	62		
INT 0198/15	miRNA based therapeutics to target pro-tumorigenic potential of stromal fibroblasts in lung cancer	L. Roz	2016		Observational	50	50	0
INT 0040/14	Role of germline and somatic DNA changes in modulating the survival of patients with lung adenocarcinoma	T. A. Dragani	2014		Observational	41	9	0
INT 0049/12	Maintainance metronomic per os Navelbine in advanced NSCLC patients after previous platinum based chemotherapy: a multicenter randomized best supportive care controlled phase II study MANILA	M. Platania	2012		II	39	8	Closed accrual
INT 0063/12	Phase II study of oral PHA-848125AC in patients with thymic carcinoma previously treated with chemotherapy	M. Garassino	2012	27/11/2017	II	36	Closed accrual	
INT 0107/15	A Phase III open-label, multicenter trial of Avelumab (MSB0010718C) versus Docetaxel in subjects with non-small cell lung cancer that has progressed after a platinum-containing doublet	M. Garassino	2015		III	33	30	Closed accrual
INT 0206/14	Cancer therapy through TLR-induced local innate immunity activation and block of immune checkpoints or suppressive cells	A. Balsari	2015	20/12/2017	Observational	30		
INT 0045/13	A Phase II study of the BRAF inhibitor Dabrafenib as a single agent and in combination with the MEK inhibitor Trametinib in subjects with BRAF V600E mutation positive metastatic (stage IV) non-small cell lung cancer	N. Zilembo	2014	12/01/2017	II	27		
INT 0068/16	A phase II prospective, single blinded, randomized trial of Hemopatch compared to standard techniques to achieve air leak control after complex thoracic surgical procedures on high risk population for prolonged air leak (> 5 days - PAL)	U. Pastorino	2016	02/04/2017	-	25	8	Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0132/14	A Phase III, Open Label, Randomized Study of AZD9291 versus Platinum-Based Doublet Chemotherapy for Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer whose Disease has Progressed with Previous Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor Therapy and whose Tumours harbour a T790M mutation within the Epidermal Growth Factor Receptor Gene (AURA3)	M. Garassino	2014		III	21		
INT 0091/14	Decurarization After Thoracic Anesthesia - Studio prospettico multicentrico randomizzato in doppio cieco per confrontare la gestione del reversal del blocco neuromuscolare con sugammadex e neostigmina dopo chirurgia toracica	F. Piccioni	2015		IV	20	0	12
INT 0092/15	A phase III, open-label, randomized study of MPDL3280A (anti-PDL1 antibody) compared with Cisplatin or Carboplatin+Pemetrexed for PD-L1-selected chemotherapy naive patients with stage IV non-squamous non-small cell lung cancer	M. Garassino	2015		III	18	0	15
INT 0011/16	A Randomized, Double-Blind, Phase III Study of Platinum+Pemetrexed Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Nonsquamous Non-small Cell Lung Cancer Subjects (KEYNOTE-189)	M. Garassino	2016		III	17	9	Closed accrual
INT 0034/13	Phase II study of oral PHA-848125AC in patients with malignant thymoma previously treated with multiple lines of chemotherapy	M. Garassino	2013	25/11/2017	II	16	Closed accrual	
INT 0099/13	Phase I Study of Single Agent MK-3475 in Patients with Progressive Locally Advanced or Metastatic Carcinoma, Melanoma, and Non-Small Cell Lung Carcinoma	M. Garassino	2013	01/01/2017	I	16		
INT 0165/15	A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy or MEDI4736 Monotherapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) (MYSTIC)	M. Garassino	2015		III	16	Closed accrual	



SCIENTIFIC REPORT 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0166/14	A Randomized Open-Label Phase III Trial of Pembrolizumab versus Platinum based Chemotherapy in 1L Subjects with PD-L1 Strong Metastatic Non-Small Cell Lung Cancer	M. Garassino	2014	01/01/2017	III	15		
INT 0055/15	A phase I, multi-center, open label, drug-drug interaction study to assess the effect of Ceritinib on the pharmacokinetics of Warfarin and Midazolam administered as a two-drug cocktail in patients with ALK-positive advanced tumors including non-small cell lung cancer (NSCLC)	F. De Braud	2016	12/12/2017	I	14	7	Closed accrual
INT 0098/12	PASS Pleural mesothelioma Strategies Study	U. Pastorino	2014		-	13	6	0
INT 0165/16	Phase II trial of Sunitinib in patients with type B3 thymoma or thymic carcinoma in second and further lines (Style trial)	M. Garassino	2017		II	13		13
INT 0137/12	An Open-Label Randomized Phase III Trial of BMS-936558 versus Docetaxel in Previously Treated Metastatic Non-squamous Non-small cell Lung Cancer (NSCLC)	M. Garassino	2013		III	11		
INT 0114/15	A Phase II, multi-center, open-label, five-arm study to evaluate the efficacy and safety of oral ceritinib treatment for patients with ALK-positive non-small cell lung cancer (NSCLC) metastatic to the brain and/or to leptomeninges	M. Platania	2015		II	10	7	Closed accrual
INT 0117/16	A phase I/III, randomized, double-blind, placebo-controlled study of Carboplatin Plus Etoposide with or without Atezolizumab (anti-PD-L1 antibody) in patients with untreated extensive-stage small cell lung cancer	M. Garassino	2016		I/III	10	4	Closed accrual
INT 0061/13	POST-ALK: observational study of treatment and outcome after Crizotinib in advanced ALK-positive NSCLC patients	M. Garassino	2013		Observational	9	0	0
INT 0100/12	An Open-label Randomized Phase III Trial of BMS-936558 versus Docetaxel in Previously Treated Advanced or Metastatic Squamous Cell Non-small Cell Lung Cancer (NSCLC)	M. Garassino	2013		III	8		

ONGOING CLINICAL STUDIES 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0056/15	A Phase III, Open label, Randomised, Multicentre, International Study of MED14736, given as monotherapy or in combination with tremelimumab determined by PO-L1 expression, versus Standard of Care in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer (Stage IIIB-IV) Who Have Received at Least Two Prior Systemic Treatment Regimens Including One Platinum-based Chemotherapy Regimen and Do Not Have Known EGFR TK Activating Mutations or ALK Rearrangements (ARCTIC)	M. Garassino	2015		III	8	Closed accrual	
INT 0135/15	A Phase II multicenter, randomized, placebo controlled, double-blind study to assess the safety and efficacy of CC-486 (oral Azacitidine) in combination with Pembrolizumab (MK-3475) versus Pembrolizumab Plus placebo in subjects with previously treated locally advanced or metastatic non-small cell lung cancer	M. Garassino	2016	31/12/2017	II	7	Closed accrual	
INT 0137/16	A phase II randomized study of Pembrolizumab in patients with advanced malignant pleural mesothelioma	M. Garassino	2017		II	7		Closed accrual
INT 0090/15	A multi-center, open-label study to assess the safety and efficacy of combination Ceritinib (LDK378) and Nivolumab in adult patients with anaplastic lymphoma kinase (ALK) - positive non-small cell lung cancer (NSCLC)	F. De Braud	2015		I	6	0	0
INT 0190/15	A randomized, phase III trial with anti-PD-1 monoclonal antibody Pembrolizumab (MK-3475) versus placebo for patients with early stage NSCLC after resection and completion of standard adjuvant therapy	M. Garassino	2016		III	6	2	4
INT 0136/16	A randomized open-label phase III trial comparing Bevacizumab + Erlotinib vs Erlotinib alone as first line treatment of patients with EGFR mutated advanced non squamous non small cell lung cancer	M. Garassino	2017		III	6		6
INT 0043/17	A Phase III, Randomized, Multicenter, Open-Label, Comparative Study to Determine the Efficacy of Durvalumab or Durvalumab and Tremelimumab in Combination With Platinum-Based Chemotherapy for the First-Line Treatment in Patients with Extensive Disease (Stage IV) Small-Cell Lung	M. Garassino	2017		III	6		6



SCIENTIFIC REPORT 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0166/15	An Open-label, Randomized, Phase III Study of Nivolumab or Chemotherapy in Subjects with Relapsed Small-cell Lung Cancer after Platinum-based First Line Chemotherapy	N. Zilembo	2016		III	6	Closed accrual	
INT 0142/17	An open-label, multi-center, Phase IV, roll-over study in patients with ALK positive malignancies who have completed a prior Novartis-sponsored Ceritinib (LDK378) study and are judged by the investigator to benefit from continued treatment with Ceritinib	F. De Braud	2017		IV	5		5
INT 0107/16	A randomized, open-label, active-controlled, Phase II study of intravenous Anetumab Ravtansine (BAY 94-9343) or Vinorelbine in patients with advanced or metastatic malignant pleural mesothelioma hyperexpressing mesothelin and progressed on first line platinum/Pemetrexed-based chemotherapy	M. Garassino	2016		II	5	Closed accrual	
INT 0019/15	Randomized, multicenter, phase III, open-label study of Alectinib versus Crizotinib in treatment-naive anaplastic lymphoma kinase-positive advanced non-small cell lung cancer	M. Platania	2015		III	5		
INT 0039/17	An open label Phase Ib dose escalation study to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and maximum tolerated dose of Anetumab Ravtansine in combination with Pemetrexed 500 mg/m ² and Cisplatin 75 mg/m ² in subjects with mesothelinexpressing	N. Zilembo	2017		I	4		4
INT 0147/16	A double-blind, placebo controlled, randomized multicenter Phase II Study evaluating Gemcitabine with or without Ramucirumab as II line treatment for advanced malignant pleural mesothelioma	M. Garassino	2017		II	4		4
INT 0013/13	A Phase IB/II, open label, multicenter study of INC280 administered orally in combination with Gefitinib in adult patients with EGFR mutated, c-MET-amplified non-small cell lung cancer who have progressed after EGFR inhibitor treatment	F. De Braud	2014		I/II	4		
INT 0078/13	An open label trial of Afatinib in treatment-naive (1st line) or chemotherapy pre-treated patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring EGFR mutation(s)	N. Zilembo	2014		III	4		

ONGOING CLINICAL STUDIES 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0131/14	A phase III, randomised, double-blind, placebo-controlled, multi-centre, international study of MEDI4736 as sequential therapy in patients with locally advanced, unresectable non-small cell lung cancer (stage III) who have not progressed following definitive, platinum-based, concurrent chemoradiation therapy (PACIFIC)	M. Garassino	2015		III	4	Closed accrual	
INT 0125/15	A single-arm, open-label, Phase II study evaluating the efficacy, safety and pharmacokinetics of HM61713 in patients with T790M-positive non-small cell lung cancer (NSCLC) after treatment with an epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI)	N. Zilembo	2016	29/06/2017	II	3	Closed accrual	
INT 0128/15	An Open-Label, Randomized Phase III Trial of Nivolumab, or Nivolumab plus Ipilimumab, versus platinum doublet chemotherapy in Subjects with Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)*	M. Garassino	2016		III	3	3	Closed accrual
INT 0204/16	Post-authorisation Safety (PAS) Observational Cohort Study to Quantify the Incidence and Comparative Safety of Selected Cardiovascular and Cerebrovascular Events in COPD Patients Using Inhaled UMEC/VI Combination or Inhaled UMEC versus Tiotropium (Study 201038).	R. Boffi	2017		Observational	1		1
INT 0116/17	A Phase III, randomized, open-label study of Lorlatinib (PF-06463922) monotherapy versus Crizotinib monotherapy in the first-line treatment of patients with advanced ALK-positive non-small cell lung cancer	N. Zilembo	2017		III	1		1
INT 0053/05	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	U. Pastorino	2006	22/10/2016	-	4.099		
INT 0027/09	Randomized phase II study of NGR-hTNF in combination with standard chemotherapy versus standard chemotherapy alone in previously untreated patients with advanced non-small cell lung cancer (NSCLC)	N. Zilembo	2009	25/10/2016	II	31		



SCIENTIFIC REPORT 2016-2017

LUNG CANCER

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0066/09	Multicenter phase III randomized study of Cisplatin and Etoposide with or without Bevacizumab as first-line treatment in extensive stage (ED) small cell lung cancer (SCLC)	N. Zilembo	2013	31/12/2016	III	4		
INT 0045/10	An exploratory phase II study of Pemetrexed and Ciplatin as preoperative chemotherapy in the treatmetnet of stage IIIAN2 nonsquamous non small cell lung cancer	U. Pastorino	2010	11/03/2016	II	13		
INT 0072/10	The airINTRial: a prospective randomized phase III trial of the use of different modalities of pleural aspiration for the management of breath loss after lung surgical resection	F. Leo	2011	31/12/2016	-	580	Closed accrual	
INT 0092/11	Phase III randomized, open-label study of the efficacy and safety of Crizotinib versus Pemetrexed/Cisplatin or Pemetrexed/Carboplatin in previously untreated patients with non-squamous carcinoma of the lung harboring a traslocation or inversion event involving the anaplastic lymphoma kinase (alk) gene locus	F. De Braud	2012	28/11/2016	III	2		
INT 0091/13	LUME Study - Long survivors in pleural mesothelioma	G. Gatta	2014	30/01/2016	Observational	2.534	Closed accrual	
INT 0172/13	A single arm, open-label, phase II study to assess the efficacy and safety of Lucitanib given orally as a single agent to patients with advanced/metastatic lung cancer and FGF, VEGF, or PDGF-related genetic alterations	M. Garassino	2014	07/10/2016	II	11		
INT 0204/14	Targeting KRAS mutations in NSCLC through LKB1 co-vulnerability	M. Garassino	2015	31/12/2016	Observational	167	Closed accrual	
INT 0058/15	A Randomized, Double-Blind Phase II Study of Ruxolitinib or Placebo in Combination With Pemetrexed/Cisplatin and Pemetrexed Maintenance for Initial Treatment of Subjects With Nonsquamous Non-Small Cell Lung Cancer That Is Stage IIIB, Stage IV, or Recurrent	M. Platania	2015	11/02/2016	II	2	Closed accrual	
INT 0093/15	A phase III, open-label, randomized study of mpdl3280a (anti-pd11 antibody) compared with Gemcitabine+ Cisplatin or Carboplatin for pd-l1-selected, chemotherapy naive patients with stage IV squamous non-small cell lung cancer	M. Garassino	2015	20/04/2016	III	2	Closed accrual	
INT 0147/15	Continuity of cAre in Thoracic Tumor	M. Garassino	2015	31/12/2016	Observational	229	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

MELANOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0196/15	Exploration of CD30-associated immunosuppression signals in the sentinel node of melanoma patients	M. Rodolfo	2016		Observational	536	250	286
INT 0039/11	Identification of circulating microRNAs as potential indicators of progression in metastatic melanoma	L. Rivoltini	2011		Observational	352	29	24
INT 0027/14	Immunomodulatory effect of Esomeprazole antitumoral and high-dose in patients with melanoma in stage III. Multi-stage pilot study (AdESOM2)	L. Rivoltini	2014	21/11/2017	II	109	Closed accrual	
INT 0040/11	A study of immunomodulatory effect of BRAF and MEK inhibitors in melanoma patients	L. Rivoltini	2011		Observational	93	3	0
INT 0124/13	Identification of molecular markers of multiple cutaneous melanoma - MULTIMELMARKERS	L. Rivoltini	2014	21/11/2017	-	61	0	Closed accrual
INT 0031/15	A Phase III, Randomized, Double-blind Study of Adjuvant Immunotherapy with Nivolumab versus Ipilimumab after Complete Resection of Stage IIIb/c or Stage IV Melanoma in Subjects who are at High Risk for Recurrence	M. Del Vecchio	2015		III	42		
INT 0023/12	A Randomized Double-Blind phase III study of Ipilimumab Administered at 3 mg/kg vs at 10 mg/kg in subjects with previously treated or untreated unresectable or metastatic melanoma	M. Del Vecchio	2012	26/07/2017	III	40		
INT 0143/12	COMBI-AD: A phase III randomized double blind study of Dabrafenib (GSK2118436) in COMBInation with Trametinib (GSK1120212) versus two placebos in the ADjuvant treatment of high-risk BRAF V600 mutation-positive melanoma after surgical resection.	M. Santinami	2013		III	39		
INT 0205/14	Interference with AKT-mediated drug-resistance mechanisms to target aggressive ovarian carcinoma	P. Perego	2016	31/12/2017	Observational	30	30	Closed accrual
INT 0170/14	A Single-Arm, Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) for Subjects with Histologically Confirmed Stage III (unresectable) or Stage IV Melanoma Progressing Post Prior Treatment Containing an Anti-CTLA-4 Monoclonal Antibody	M. Del Vecchio	2015		II	25	Closed accrual	
INT 0092/17	Liquid biopsy-based assays for early diagnosis of relapse in stage III-IV surgical melanoma patients	M. Rodolfo	2017		Observational	21		21



SCIENTIFIC REPORT 2016-2017

MELANOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0038/12	A phase III, randomized, double-blinded study comparing the combination of the BRAF inhibitor, Dabrafenib and the MEK inhibitor, Trametinib to Dabrafenib and placebo as first-line therapy in subjects with unresectable (Stage IIIC) or metstatic (STAGE IV) BRAF V600E/K mutation-positive cutaneous melanoma	F. De Braud	2012		III	20		
INT 0134/15	A Phase I/II Study to Assess the Safety and Efficacy of MK-3475 in Combination with Trametinib and Dabrafenib in Subjects with Advanced Melanoma	M. Del Vecchio	2016		I/II	14	11	3
INT 0176/17	A Phase III, Randomized Study of Adjuvant Immunotherapy with Nivolumab Combined with Ipilimumab Versus Nivolumab Monotherapy after Complete Resection of Stage IIIb/c/d or Stage IV Melanoma.	M. Del Vecchio	2017		III	14		14
INT 0094/13	A Phase III, Randomized, Double-Blind Study of Nivolumab Monotherapy or Nivolumab Combined with Ipilimumab Versus Ipilimumab Monotherapy in Subjects with Previously Untreated Unresectable or Metastatic Melanoma	M. Del Vecchio	2013		III	14		
INT 0052/12	A phase III, randomised, open-label study comparing the combination of the BRAF inhibitor, Dabrafenib and the MEK inhibitor, Trametinib to the BRAF inhibitor Vemurafenib in subjects with unresectable (stage IIIC) or metastatic (stage IV) BRAF V600E/K mutation positive cutaneous melanoma	M. Del Vecchio	2013		III	13		
INT 0060/14	"The NEMO trial (NRAS melanoma and MEK inhibitor): A randomized Phase III, open label, multicenter, two-arm study comparing the efficacy of MEK162 versus dacarbazine in patients with advanced unresectable or metastatic NRAS mutation-positive melanoma"	M. Del Vecchio	2014		III	12		
INT 0089/16	Clinical Trial of Nivolumab (BMS-936558) Combined with Ipilimumab Followed by Nivolumab Monotherapy as First-Line Therapy of Subjects with Histologically Confirmed Stage III (Unresectable) or Stage IV Melanoma	M. Del Vecchio	2016		III	12	6	Closed accrual
INT 0042/13	A Phase III, Randomized, Double-Blind Study of BMS-936558 vs Dacarbazine in Subjects with Previously Untreated Unresectable or Metastatic Melanoma	F. De Braud	2013		III	11		

ONGOING CLINICAL STUDIES 2016-2017

MELANOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0044/13	A randomized, Phase III study of Fotemustine versus the Combination of Fotemustine and Ipilimumab in Patients with Metastatic Melanoma with brain metastasis	M. Del Vecchio	2013		III	10	0	1
INT 0086/16	A Phase III Randomized, Double-Blind, Placebo-Controlled Study of Pembrolizumab (MK-3475) in Combination With Epacadostat or Placebo in Subjects with Unresectable or Metastatic Melanoma (Keynote-252 / ECHO-301)	M. Del Vecchio	2016		III	9	8	Closed accrual
INT 0142/15	A pivotal Phase III, open-label, randomized, controlled multi-center study of the efficacy of L19IL2/L19TNF neoadjuvant intratumoral treatment followed by surgery versus surgery alone in clinical stage III B/C melanoma patients	M. Santinami	2016		III	7	5	2
INT 0179/16	A phase III, double blinded, randomized, placebo-controlled study of Atezolizumab PlusCobimetinib and Vemurafenib versus placebo plus Cobimetinib and Vemurafenib in previously untreated BRAFV600 mutation-positive patients with metastatic or unresectable locally advanced melanoma	M. Del Vecchio	2017		III	6		6
INT 0044/16	Phase IIb/IV. Randomized, Double Blinded, Study of Nivolumab 3 mg/kg in Combination with Ipilimumab 1 mg/kg vs Nivolumab 1 mg/kg in Combination with Ipilimumab 3 mg/kg in Subjects with Previously Untreated, Unresectable or Metastatic Melanoma	M. Del Vecchio	2016		IV	5	Closed accrual	
INT 0044/14	A Phase II, Open-Label, Multicentre Study of Dabrafenib plus Trametinib in Subjects with BRAF Mutation-Positive Melanoma that has Metastasized to the Brain	M. Del Vecchio	2014		II	4	Closed accrual	
INT 0043/16	A Phase Ib/III, Multicenter, Trial of Talimogene Laherparepvec in Combination With Pembrolizumab (MK-3475) for Treatment of Unresectable, Stage IIIB to IVM1c Melanoma (MASTERKEY-265)	M. Del Vecchio	2017		III	1		1
INT 0044/17	A randomized, double-blind, placebo-controlled, phase III study comparing the combination of PD1001, Dabrafenib and Trametinib versus placebo. Dabrafenib and Trametinib in previously untreated patients with unresectable or metastatic BRAF V600 mutant melanoma	M. Del Vecchio	2017		I/III	1		1



SCIENTIFIC REPORT 2016-2017

MELANOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0093/17	Pattern of response/progression to first line treatment with Dabrafenib and Trametinib in patients with Unresectable or Metastatic BRAF Mutation-Positive Cutaneous Melanoma: the T-WIN study	M. Del Vecchio	2017		Observational	1		1
INT 0164/16	A three arms prospective, randomized phase II study to evaluate the best sequential approach with combo immunotherapy (ipilimumab/nivolumab) and combo target therapy (LGX818/ MEK162) in patients with metastatic melanoma and BRAF mutation	M. Del Vecchio	2017		II	1		1
INT 0062/10	An open phase I study of immunization with the rec-NY-ESO-1 + AS15 antigen-specific cancer immunotherapeutic in patients with NY-ESO-1 positive unresectable and progressive metastatic cutaneous melanoma	M. Santinami	2011	29/02/2016	I	26		
INT 0001/11	A phase III randomized, open-label study comparing GSK1120212 to chemotherapy in subjects with advanced or metastatic BRAFV600E/K mutation-positive melanoma	M. Del Vecchio	2011	05/12/2016	III	5		
INT 0037/12	Malignant skin lesions in patients with cancer: an observational prospective study	A. T. Caraceni	2012	01/07/2016	Observational	103	Closed accrual	
INT 0103/12	A multicentre, open label, randomized Phase II trial of the MEK inhibitor Pimasertib or Dacarbazine in previously untreated subjects with N-Ras mutated locally advanced or metastatic malignant cutaneous melanoma	F. De Braud	2012	14/04/2016	II	8		
INT 0140/12	A Randomized, Open-Label Phase III Trial of BMS-936558 versus Investigator's Choice in Advanced (Unresectable or Metastatic) Melanoma Patients Progressing Post Anti-CTLA-4 Therapy	M. Del Vecchio	2013	15/02/2016	III	2		
INT 0117/13	ZeSS: A Prospective Observational Safety Study of Patients with BRAFV600 Mutation-positive Unresectable or Metastatic Melanoma Treated with Vemurafenib (Zelboraf®)	M. Del Vecchio	2014	28/11/2016	Observational	1		
INT 0069/14	A 2-part phase III randomized, open label, multicenter study of LGX818 plus MEK162 versus Vemurafenib and LGX818 monotherapy in patients with unresectable or metastatic BRAF V600 mutant melanoma	M. Del Vecchio	2014	17/02/2016	III	3		

ONGOING CLINICAL STUDIES 2016-2017

MELANOMA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0084/14	Overall survival of braf v600 mutated and non mutated metastatic melanoma patients: a cohort observational study of braf inhibitors and current therapies effectiveness	M. Del Vecchio	2015	31/12/2016	Observational	14		
INT 0158/14	An observational study to evaluate the effectiveness and safety of ipilimumab, administered during the European expanded access programme in pretreated patients with advanced (unresectable or metastatic) melanoma	M. Del Vecchio	2015	18/05/2016	Observational	47	Closed accrual	
INT 0103/15	Sex steroid hormones and cutaneous melanoma risk and survival	V. Krogh	2015	30/06/2016	Observational	40	Closed accrual	
INT 0075/16	Role of Melanocortin-1 Receptor variants in childhood and adolescent melanoma	B. Valeri	2016	30/12/2016	Observational	9	Closed accrual	
INT 0207/14	Targeting melanoma dedifferentiation and Epithelial-Mesenchymal Transition (EMT) to promote immunogenicity	R. Mortarini	2015		-	121	53	41
INT 0064/13	Constitution of a Clinical National Melanoma Registry (CNMR)	M. Del Vecchio	2014		-	3	0	0
INT 0209/14	Co-targeting of stress response pathways and oncogenic pathways to identify new therapeutic targets in melanoma	A. Anichini	2015	42370	-	72	Closed accrual	

MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0073/16	EUROCARE-6 Protocol for updating population-based cancer survival in Europe	M. Sant	2015	17/02/2017	Observational	51622		0
INT 0085/13	Randomized controlled trial of metformin and dietary restriction to prevent age-related morbid events in people with metabolic syndrome	F. Berrino	2014		III	1515	332	845
INT 0166/13	Novel molecular mechanisms of genetic predisposition to early-onset breast cancer	P. Radice	2014		Observational	1300	0	0
INT 0032/09	Epidemiologic studies on environmental risk factors and their interactions with genetic factors of bladder cancer and sarcomas	A. Decarli	2011		Observational	1186	114	Closed accrual



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MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0197/14	HIGHCARE: HIGH resolution project on prognosis and CARE of cancer patients	M. Sant	2016		Observational	999	999	0
INT 0008/12	Hypercoagulation screening as an innovative tool for risk assessment, early diagnosis and prognosis in cancer	F. De Braud	2012	30/01/2017	Observational	749	144	66
INT 0035/09	Efficacy of thermal treatment for respiratory airways in heavy smokers	U. Pastorino	2010		Observational	468		
INT 0024/14	"REQUITE Study Protocol Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life in cancer survivors "	R. Valdagni	2014		Observational	325	63	Closed accrual
INT 0098/16	Survey about oncological patient satisfaction with Radiation Therapists (RT) care in Radiation Oncology Unit and evaluation about the use of humor during interactions between patients and RT	S. Frasca	2016		Observational	248	113	Closed accrual
INT 0135/17	Translation and cultural adaptation of the PG-SGA to the Italian setting	C. Ripamonti	2017		Observational	201		201
INT 0011/17	MICRObiota, infLammatory Environment, clinicAl and Radiomic features as predictors of Normal tissue response in radiotherapy for prostatE and head-and-neck canceR (MICRO-LEARNER)	R. Valdagni	2017		Observational	136		136
INT 0008/14	Comparison pilot study between complex decongestive therapies for the treatment of secondary lower limbs lymphedema in cancer patients	A. T. Caraceni	2014		-	135	8	112
INT 0151/15	Observational study designed to evaluate the prognostic and predictive impact of factors related to immunity in cancer patients treated with immunotherapy	M. Di Nicola	2015	07/10/2016	Observational	101	18	48
INT 0102/15	Is the protective effect of mediterranean diet on cancer mediated by a methylation pattern?	V. Krogh	2015		Observational	100	0	Closed accrual
INT 0039/12	A phase I dose escalation study of RXDX-101 in adult patients with advanced/metastatic solid tumors	F. De Braud	2012		I	47	2	0
INT 0059/12	Identification of polymorphisms predicting Bevacizumab-related side effects: SToPtrial	M. Di Bartolomeo	2012	25/07/2017	Observational	73	1	0
INT 0010/17	Safety, Feasibility and Metabolic Effects of the Fasting Mimicking Diet (FMD) in Cancer Patients	F. De Braud	2017		-	64		64

ONGOING CLINICAL STUDIES 2016-2017

MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0075/12	A Phase Ia/Ib, Multi-Center, Open-Label, Dose Finding Study to Assess the Safety, Tolerability, Pharmacokinetics and Preliminary Efficacy of the Pleiotropic Pathway Modifier CC-122 Administered Orally to Subjects with Advanced Solid Tumors, Non-Hodgkin's Lymphoma or Multiple Myeloma	F. De Braud	2013	13/12/2017	I	10	2	0
INT 0054/16	Comparison between protective and non restrictive diet in oncological patients with prolonged neutropenia	P. Corradini	2016		-	58	23	35
INT 0122/12	Phase Ib study of the tumor-targeting human L19TNFalpha monoclonal antibody-cytokine fusion protein in combination with doxorubicin in patients with advanced solid tumours	F. De Braud	2013	28/04/2017	I	9	0	0
INT 0010/13	A Phase I open-label dose escalation study with expansion to assess the safety and tolerability of INC280 in patients with c-MET dependent advanced solid tumors	F. De Braud	2013	09/04/2016	I	26	Closed accrual	
INT 0027/15	Palliative radiotherapy of bone metastasis. Classification, inflammatory biomarkers, and longitudinal clinical follow-up	L. Lozza	2015		Observational	49	21	Closed accrual
INT 0051/17	Monocenter, open label clinical investigation on the treatment with xonrid®, a medical device for the prevention and treatment of radiotherapy-induced dermatitis, in breast and head & neck cancer patients receiving curative treatment	E. Orlandi	2017		-	48		48
INT 0076/13	"An open label phase I dose finding study of BI 860585 administered orally in a continuous dosing schedule as single agent and in combination with exemestane or with paclitaxel in patients with various advanced and/or metastatic solid tumours"	F. De Braud	2013		I	28	Closed accrual	
INT 0042/11	SUTNET Trial: biological and clinical phase II study of Sunitinib in patients with unresectable and/or metastatic pheochromocytomas/paragangliomas	R. Buzzoni	2012	20/12/2017	II	45	2	6
INT 0183/13	Effects of high Intra-abdominal pressure on tissue diffusion and pharmacokinetics of cisplatin during HIPEC Experimental evidence of tolerance to high intra abdominal pressure (IAP) during HIPEC	S. Kusamura	2014		II	43	10	Closed accrual
INT 0176/15	A Phase I/II, open label, multicenter study of the safety and efficacy of LAG525 single agent and in combination with PD1001 administered to patients with advanced malignancies	F. De Braud	2016	07/10/2016	I/II	41	14	27



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MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0076/17	Changes of eating habits during oncological treatments	R. Mazza	2017		Observational	40		Closed accrual
INT 0077/13	Dose escalation, safety, pharmacokinetic and pharmacodynamic, first in man study, of SAR125844 single agent administered as slow intravenous infusion in adult patients with advanced malignant solid tumors	F. De Braud	2013		I	63		
INT 0112/11	Toremifene in desmoid tumor: prospective clinical trial and identification of potential molecular targets	C. Colombo	2012		II	30	3	Closed accrual
INT 0040/16	Observational retrospective and prospective multicenter study, to assess prescribing appropriateness of new drugs for the treatment of chronic hepatitis C and the development of liver disease at 12 months after treatment	G. Saibene	2016	08/02/2017	Observational	30	30	Closed accrual
INT 0170/13	A phase I/II, open-label study of Nivolumab monotherapy or Nivolumab combined with Ipilimumab in subjects with advanced or metastatic solid tumors	F. De Braud	2014		I/II	74	23	Closed accrual
INT 0097/17	Evaluation of endobronchial ultrasound procedure anesthetic management with iGEL laryngeal mask	F. Piccioni	2017		Observational	28		Closed accrual
INT 0020/14	Phase IB study of Pembrolizumab (MK-3475) in subject with select advanced solid tumors	F. De Braud	2014		I	49		
INT 0152/14	A phase I, open-label, multi-center, dose escalation study of oral BGJ398, a pan FGF-R kinase inhibitor, in adult patients with advanced solid malignancies	F. De Braud	2015		I	7		Closed accrual
INT 0185/16	TGCT Observational Platform Project: A disease registry for patients with pigmented villonodular synovitis (PVNS) and giant cell tumor of the tendon sheath (GCT-TS), also known as tenosynovial giant cell tumors (TGCT).	S. Stacchiotti	2017	30/05/2016	Observational	21		21
INT 0006/13	Cross-tumoral phase II clinical trial exploring Crizotinib (PF-02341066) in patients with advanced tumors induced by causal alterations of ALK and/or MET ("CREATE")	P. G. Casali	2013	18/07/2017	II	20	2	Closed accrual
INT 0005/15	Longitudinal genotyping or circulating tumor DNA in patients with metastatic solid tumors responding to targeted therapies to understand and monitor drug resistance	F. De Braud	2015		Observational	36	6	0

ONGOING CLINICAL STUDIES 2016-2017

MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0169/15	Translation, cross-cultural adaptation and validation of the US national cancer institute's patient-reported outcomes version of the common terminology criteria for adverse events (PRO-CTCAE) for Italian-speaking cancer patients	G. Procopio	2016		Observational	13	5	Closed accrual
INT 0120/15	A multicenter, translational study to investigate the genomic landscape of cancer of unknown primary (CUP): AGNOSTOS PROFILING study	F. De Braud	2016		Observational	11	5	6
INT 0004/15	Prospective study for the determination of the molecular profile of resistance to "target therapies" in patients with solid tumors - Protocol PROFILING	F. De Braud	2015		Observational	17	5	6
INT 0033/15	A phase I, multicenter, open-label dose escalation and expansion study of PCA062, administered intravenously in adult patients with pCAD-positive tumors	F. De Braud	2015		I	24	14	4
INT 0072/15	"An open-label, multicohort, phase II study of MPDL3280A in advanced solid tumors"	F. De Braud	2015		II	50	7	Closed accrual
INT 0126/15	A phase III, multicenter, randomized, double-blind, active control study to evaluate the safety and efficacy of IV Pro-Netupitant/Palonosetron (260 mg/0.25 mg) combination for the prevention of chemotherapy-induced nausea and vomiting in repeated chemotherapy cycles in patients receiving highly emetogenic chemotherapy	L. Celio	2016		III	1	Closed accrual	
INT 0062/16	CORRELATE - Safety and effectiveness of Regorafenib in routine clinical practice settings	M. Di Bartolomeo	2016		Observational	10	9	Closed accrual
INT 0008/16	An open-label, multicenter, phase I study of Ramucirumab Plus MEDI4736 in patients with locally advanced and unresectable or metastatic gastrointestinal or thoracic malignancies	F. De Braud	2016		I	8	8	Closed accrual
INT 0048/16	An open-label, multicenter, global phase I basket study of Entrectinib for the treatment of patients with locally advanced or metastatic solid tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements	F. De Braud	2017		II	3		3
INT 0151/14	A phase II, open-label, multicenter trial to investigate the clinical activity and safety of MSB0010718C in subjects with Merkel cell carcinoma	R. Buzzoni	2015		II	8		3



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MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0047/09	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	S. Cresta	2009		I	8		
INT 0061/16	Nutritional Screening with bioelectrical impedance. Prospective, observational, multicenter study to evaluate the prognostic value of phase angle in newly detected cancer patients candidate to chemotherapy	C. Gavazzi	2016		Observational	63	22	41
INT 0105/16	A randomized, controlled, cluster stepped-wedge designed trial, evaluating a strategy to optimize psychosocial outcomes in cancer patients	G. Procopio	2016		-	7	3	4
INT 0109/15	A phase II, randomized, multicenter study to assess the efficacy of nab-paclitaxel-based doublet as first line therapy in patients with cancer of unknown primary (CUP): the AGNOSTOS trial	F. De Braud	2016		II	7	2	5
INT 0167/15	A prospective, observational study measuring sodium improvement and outcomes in cancer patients treated for moderate to severe hyponatremia secondary to SIADH	M. Garassino	2016		Observational	7	5	Closed accrual
INT 0057/14	A phase II, open-label, study in subjects with BRAF V600E mutated rare cancers with several histologies to investigate the clinical efficacy and safety of the combination therapy of Dabrafenib and Trametinib	F. De Braud	2015		II	4	1	2
INT 0034/15	A pilot study to test the feasibility of a two-arm, double blind, parallel-group, randomized controlled trial for the comparison of the duration of the analgesic efficacy of a single matrix transdermal fentanyl patch compared vs a double matrix transdermal fentanyl patch	A. T. Caraceni	2015	19/12/2016	IV	3	1	1
INT 0069/16	A phase I, open-label, multiple-ascending dose trial to investigate the safety, tolerability, pharmacokinetics, biological and clinical activity o MSB0011359C in subjects with metastatic or locally advanced solid tumors and expansion to selected indications	M. Di Nicola	2016	31/12/2016	I	11	2	9

ONGOING CLINICAL STUDIES 2016-2017

MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0121/16	A phase I/Ia dose escalation and cohort expansion study for safety, tolerability, and efficacy of BMS-986156 administered alone and in combination with Nivolumab (BMS-936558, anti-PD-1 Monoclonal Antibody) in advanced solid tumors	M. Di Nicola	2016	31/12/2016	I/II	22	10	12
INT 0166/17	Evaluation of body image, psychological well-being, and satisfaction level for use of CNC ® prosthetic system in patients with breast cancer recurrence and chemotherapy induced alopecia relapse: pilot project	C. Borreani	2017		-	2		2
INT 0046/13	An open-label, multi-center everolimus roll-over protocol for patients who have completed a previous Novartis sponsored everolimus study and are judged by the investigator to benefit from continued everolimus treatment	R. Buzzoni	2013	24/11/2016	IV	2		
INT 0080/17	Phase Ib multi-indication study of Anetumab Ravtansine (BAY 94-9343) in patients with mesothelin expressing advanced or recurrent malignancies	F. De Braud	2017		I	1		1
INT 0177/15	Multicenter, randomized, double-blind, parallel-group, placebo controlled, study to evaluate the effects of melatonin (food supplement) in the management on sleep quality and mood alteration in cancer patients	M. Platania	2016	31/12/2016	-	1	1	Closed accrual
INT 0177/16	A phase I/Ia study of BMS 986148, a Mesothelin directed antibody drug conjugate, in subjects with select advanced solid tumors	F. De Braud	2017		I/II	11		Closed accrual
INT 0104/11	An open label, multicenter, expanded access study of INC424 for patients with primary myelofibrosis (PMF) or post polycythemia myelofibrosis (PPV MF) or post-essential thrombocythemia myelofibrosis (PET-MF)	P. Corradini	2012	30/06/2016	III	7		
INT 0041/11	Prospective, phase II randomized to compare Busulfan-Fludarabine reduced-intensity conditioning (RIC) with thiotepa-fludarabine RIC regimen prior to allogeneic transplantation of hematopoietic cells for the treatment of myelofibrosis	P. Corradini	2012		II	1		
INT 0025/12	Identification and validation of microRNAs as novel biomarkers and therapeutic targets in diffuse malignant peritoneal mesothelioma	N. Zaffaroni	2012	31/12/2016	Observational	70		



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MISCELLANEA

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0020/17	A phase I/Ila study of BMS-986205 administered in combination with Nivolumab (BMS-936558, Anti-PD-1 Monoclonal Antibody) in advanced malignant tumors	F. De Braud	2017		I/II	10		10
INT 0021/13	Variation of respiratory function and chest wall mechanics after resection and rib-like costal reconstruction	F. Piccioni	2013		-	18	Closed accrual	
INT 0041/17	A phase I/Ila study of BMS-986178 administered alone and in combination with Nivolumab or Ipilimumab in advanced solid tumors	F. De Braud	2017		I/II	3		3
INT 0148/13	Procedures, complications and follow-up of tracheostomy techniques in intensive care	L. Persiani	2014		Observational	30		
INT 0048/17	A phase II, open label, multicenter, multi-arm study of Ceritinib in patients with advanced solid tumors and hematological malignancies characterized by genetic abnormalities of anaplastic lymphoma kinase (ALK)	S. Stacchiotti	2017		II	1		Closed accrual
INT 0194/14	Psychological determinants of preventive choices in BRCA1-2 carriers	C. Borreani	2015		Observational	73		
INT 0141/17	A Phase II, multi-center, open label study of NIR178 in combination with PD1001 in patients with selected advanced solid tumors and non-Hodgkin lymphoma	F. De Braud	2017		II	9		9
INT 0130/16	Follow-up after 2 years on the efficacy of Varenicline in the smoking cessation	R. Boffi	2016		Observational	233	Closed accrual	



ONGOING CLINICAL STUDIES 2016-2017

PALLIATIVE CARE

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0153/13	Interaction between clinical and genetic factors in modulation of opioid analgesia and side effects in cancer pain	A. T. Caraceni	2015		Observational	259	126	48
INT 0019/16	Postural evaluation through baropodometry and rehabilitation therapy focusing on women with breast's surgery reconstruction after radical mastectomy in breast cancer	F. Gariboldi	2016		Observational	61	Closed accrual	
INT 0079/15	A phase II, multicentre, randomized controlled study evaluating the quality of life in patients with inoperable malignant bowel obstruction treated with Lanreotide Autogel 120 mg in combination with standard care vs. standard care alone (QoL in IMBO study)	A. T. Caraceni	2015		II	5	2	1
INT 0120/14	Action - Observation Therapy in young patients with upper limb neuromotor outcomes from brain tumor	F. Gariboldi	2014	31/12/2016	Observational	7		
INT 0020/16	Effects on functional measurements of analgesic drug therapies in patients with bone metastases	F. Gariboldi	2016	31/12/2016	Observational	81	Closed accrual	
INT 0066/05	Registry of congenital malformations in Lombardy	G. Tagliabue	2006		-	36202	7670	5440
INT 0152/16	Promoting patient safety and quality improvement in critical care	R. Manzi	2016		-	3033	0	3033
INT 0105/12	The Lombardy Rare Donor Programme	F. Arienti	2012		-	316	253	0
INT 0084/15	Peritoneal Surface Oncology Group International (PSOGL) Registry on Peritoneal Mesothelioma	S. Kusamura	2015		-	224	10	12
INT 0144/15	National Data Base of BOne Metastases - NDBOM	G. Procopio	2016		-	30	14	16
INT 0161/15	Experimental tests of probe molecules encapsulation into human red blood cells aimed at the design of a device to be used on-line with the patient	A. Mazzocchi	2015		-	26	6	18



SCIENTIFIC REPORT 2016-2017

PEDIATRIC TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0103/14	Observational retrospective and prospective study on patients enrolled in AIEOP and IPINET Centers	M. Massimino	2014		Observational	709	239	236
INT 0093/12	PanCareSurFup: PanCare Childhood and Adolescent Cancer Survivor Care and Follow-up Studies	M. Terenziani	2013		Observational	164		
INT 0014/03	Wilms' tumor: diagnostic-therapeutic protocol AIEOP 2003	F. Spreafico	2003		Observational	157	14	12
INT 0016/03	Germ cell tumors: diagnostic-therapeutic protocol AIEOP 2003	M. Terenziani	2003		III	152	15	8
INT 0065/14	Complications related to indwelling central venous catheter in pediatric oncology patients	D. Codazzi	2015	06/08/2017	Observational	147	92	Closed accrual
INT 0176/13	Retrospective and prospective study of late radiation damages after focal radiotherapy for childhood brain tumors	L. Gandola	2014		Observational	89	20	10
INT 0170/16	Optimization of pediatric CT protocols	C. Morosi	2016		Observational	75	15	60
INT 0040/01	Protocol NB-AR-01: First European Cooperative Study for high-risk neuroblastoma	R. Luksch	2002		III	71	4	Closed accrual
INT 0007/12	Nimotuzumab and Vinorelbina concomitantly to radiation and as maintenance for newly diagnosed diffuse pontine glioma in childhood	M. Massimino	2012		Observational	60	12	5
INT 0072/17	Changes in dietary habits in patients during cancer treatments	M. Massimino	2017	12/09/2017	Observational	60		Closed accrual
INT 0084/10	Evaluation and treatment of bone mass and body composition alterations in pediatric patients with oncological disease of central nervous system	E. Seregni	2012		Observational	59	6	5
INT 0132/16	"Molecular studies of pediatric and adolescent's sarcomas for the identification of novel therapeuticdrugs - miRNA and gene expression profile"	G. Sozzi	2016	31/12/2017	Observational	59	59	Closed accrual
INT 0022/09	A phase III study on the efficacy of dose intensification in patients with non-metastatic Ewing's sarcoma	P. G. Casali	2009		III	55	5	12
INT 0196/16	Concordances and dicrepancies in perception of chemotherapy side effects by parents and children. Questionnaire that assesses frequency, severity and distress of 31 symptoms	S. Macchi	2017		Observational	44		44

ONGOING CLINICAL STUDIES 2016-2017

PEDIATRIC TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0017/08	HL PED 2008 Hodgkin's lymphoma. A therapeutic protocol for sequels reduction	M. Terenziani	2008		II	42	3	5
INT 0099/15	Rehabilitation and psychological features in paediatric bone sarcomas: the way from diagnosis to cure	C. Meazza	2015		Observational	35	20	11
INT 0025/09	Therapeutic protocol with high-dose chemotherapy, radiotherapy, maintenance therapy with low-dose Cyclophosphamide and anti-COX2 in metastatic Ewing's sarcoma: ISG/AIEOP study	P. G. Casali	2009		II	34	2	3
INT 0013/03	Non-controlled clinical study for the treatment of Ewing's sarcoma in relapse	R. Luksch	2003		II	24		
INT 0043/12	European Low an Intermediate Risk Neuroblastoma	R. Luksch	2013		III	22	3	9
INT 0142/14	Pathways to diagnosis project in adolescent and young adult tumors	A. Ferrari	2015	01/01/2017	Observational	20		
INT 0094/15	"Phase II open label randomized study of radiotherapy, concomitant Nimotuzumab and Vinorelbine and re-irradiation at relapse versus radiotherapy and multiple elective radiotherapy courses with concomitant Vinorelbine and Nimotuzumab for newly diagnosed childhood and adolescence diffuse intrinsic pontine glioma (dipg)"	M. Massimino	2015		III	18	11	5
INT 0185/15	"LCH-IV international collaborative treatment protocol for children and adolescents with langerhans cell histiocytosis"	M. Terenziani	2016		III	16	8	8
INT 0133/16	Molecular studies of pediatric and adolescent's sarcomas for the identification of novel therapeutic drugs- prognostic value of PDL1	G. Sozzi	2016		Observational	16	12	4
INT 0080/13	A Phase I, open-label, dose escalation study of LDK378 in pediatric patients with malignancies that have a genetic alteration in anaplastic lymphoma kinase (ALK)	M. Casanova	2013		I	16	4	Closed accrual
INT 0014/15	An international clinical program for the diagnosis and treatment of children, adolescents and young adults with ependymoma	M. Massimino	2016		II/III	14	9	5
INT 0046/11	A phase II open-label, randomized, multi-centre comparative study of Bevacizumab-based therapy in paediatric patients with newly diagnosed supratentorial high-grade glioma	M. Massimino	2011		II	14		



SCIENTIFIC REPORT 2016-2017

PEDIATRIC TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0061/17	A retrospective study of Bone Marrow Transplantation Working Group-AIEOP on the compassionate use of plerixafor in pediatric patients candidate to autologous transplantation	R. Luksch	2017		Observational	12		12
INT 0059/17	A European Society for Pediatric Oncology (SIOP-E) retrospective, integrative clinical, radiology, pathology and molecular biology analysis of pediatric High-Grade Glioma (pHGG) for the Purpose of Developing a Survival Prediction Tool	M. Massimino	2017	15/11/2017	Observational	11		Closed accrual
INT 0103/13	A Phase I/II, multicenter, open-label, dose-finding study to assess the safety, tolerability, and preliminary efficacy of weekly nab®-paclitaxel in pediatric patients with recurrent or refractory solid tumors	M. Casanova	2014		I/II	11	2	Closed accrual
INT 0172/14	Phase I/II study of Lenvatinib in children and adolescents with refractory or relapsed solid malignancies	M. Casanova	2015		I/II	10	1	6
INT 0013/08	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	M. Casanova	2008		II	10		
INT 0012/16	Phase I open label, dose escalation trial to determine the MTD, safety, PK and efficacy of afatinib monotherapy in children aged 2 years to <18 years with recurrent/refractory neuroectodermal tumours, rhabdomyosarcoma and/or other solid tumours with known ErbB pathway deregulation regardless of tumour histology	M. Casanova	2016		I	9	9	0
INT 0087/15	An early-phase, multicenter, open-label study of the safety and pharmacokinetics of anti-PD-L1 antibody (MPDL3280A) in pediatric and young adult patients with previously treated solid tumors	M. Casanova	2015		I	8	4	Closed accrual
INT 0014/13	Intergroup trial for children or adolescents with b-cell NHL or B-AL: evaluation of Rituximab efficacy and safety in high risk patients	F. Spreafico	2013		II/III	7	1	Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

PEDIATRIC TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0175/13	An international prospective study on clinically standard-risk Medulloblastoma in children older than 3 to 5 years with low-risk biological profile (PNET 5 MB -LR) or average-risk biological profile (PNET 5 MB - SR)	M. Massimino	2016		II/III	6	3	3
INT 0091/15	International randomised controlled trial of chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	R. Luksch	2016		II/III	5	2	3
INT 0016/13	A phase I/II dose schedule finding study of CH14.18/CHO continuous infusions combined with subcutaneous aldesleukin (IL-2) in patients with primary refractory or relapsed neuroblastoma. A SIOPEN Study	R. Luksch	2013		I/II	4	1	0
INT 0183/16	MoleculAr Profiling for Pediatric and Young Adult Cancer Treatment Stratification - MAPPYACTS	M. Casanova	2017		-	3		3
INT 0049/11	International randomized phase II trial of the combination of Vincristine and Irinotecan with or without Temozolomide (VIT or VIT) in children and adults with refractory or relapsed rhabdomyosarcoma	M. Casanova	2012		II	3	0	1
INT 0005/13	Re-induction protocol for patients with high-risk neuroblastoma at first relapse	R. Luksch	2013		II	3	1	Closed accrual
INT 0140/14	Prospective study registry of peripheral neuroblastic tumours patients presenting with spinal canal involvement (SCI)	R. Luksch	2016		Observational	2	1	1
INT 0029/17	A phase I study of the EZH2 inhibitor Tazemetostat in pediatric subjects with relapsed or refractory INHL-Negative Tumors or Synovial Sarcoma	M. Casanova	2017		I	2		2
INT 0053/10	Phase I/II combined dose ranging and randomised, open-label, comparative study of efficacy and safety of Plerixafor in addition to standard regimens for mobilisation of haematopoietic stem cells into peripheral blood, and subsequent collection by apheresis, versus standard mobilisation regimens alone in pediatric patients, aged 2 to <18 years, with solid tumours eligible for autologous transplants	R. Luksch	2012	06/03/2017	I/II	2		
INT 0062/11	First International Inter-Group Study for nodular lymphocyte-predominant Hodgkin's Lymphoma in Children and Adolescents	M. Terenziani	2015		IV	1	0	0



SCIENTIFIC REPORT 2016-2017

PEDIATRIC TUMORS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0082/16	A phase I/II, multicenter, open-label, dose-escalation study of the safety and pharmacokinetics of Cobimetinib in pediatric and young adult patients with previously treated solid tumors	M. Casanova	2016		I/II	1	1	0
INT 0049/17	A Phase I/II Study of the Oral TRK Inhibitor LOXO-101 in Pediatric Patients with Advanced Solid or Primary Central Nervous System Tumors	M. Casanova	2017		I/II	1		1
INT 0087/17	A phase II clinical study of Pomalidomide (CC-4047) monotherapy for children and young adults with recurrent or progressive primary brain tumors	M. Massimino	2017		II	1		1
INT 0026/95	Immunotherapy (IL-2 and activated circulating mononuclear cells) and pre/post-surgical antineoplastic chemotherapy in the primary treatment of osteosarcoma	C. Meazza	1995	31/12/2016	II	90	Closed accrual	
INT 0012/03	Second protocol for diagnosis and treatment of ependymoma in a pediatric age	M. Massimino	2004	30/06/2016	Observational	53		
INT 0145/12	A Phase II, multi-center, open-label, single-arm study of the efficacy and safety of oral LDE225 in patients with Hhpathway activated relapsed medulloblastoma	M. Casanova	2013	07/09/2016	II	5		
INT 0126/14	REACT: REsources in Adolescent Cancer Treatment	C. A. Clerici	2014	31/07/2016	Observational	45	Closed accrual	
INT 0127/14	Quality of life in long-term survivors pediatric patients treated for metastatic medulloblastoma	M. Massimino	2014	31/10/2016	Observational	25	Closed accrual	
INT 0097/16	Measuring the efficacy of a project for adolescents and young adults with cancer: a study from the Milan Youth Project	A. Ferrari	2016	31/08/2016	Observational	48	Closed accrual	
INT 0153/15	DIPG Registry and Imaging Repository	M. Massimino	2017		-	79		79
INT 0139/14	Italian peripheral neuroblastic tumors Registry (RINB) - AIEOP (Italian Association of Pediatric Hematology Oncology) Registry	R. Luksch	2014		-	44	15	14
INT 0175/14	Identification of potential targets for therapy and expression of immune inhibitors in the neoplastic stroma in patients with neuroblastoma	R. Luksch	2015		-	22	14	3

ONGOING CLINICAL STUDIES 2016-2017

SARCOMAS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0032/05	EpSSG NRSTS 2005. A protocol for localized non-rhabdomyosarcoma soft tissue sarcomas	A. Ferrari	2005		III	191	Closed accrual	
INT 0085/10	Evaluation of the role of immunosuppressive mechanisms in the prognosis and response to treatment with targeted therapy drugs in sarcoma patients	L. Rivoltini	2011		Observational	188	5	6
INT 0168/16	Do surgical gloves and instruments harbour malignant cells?	M. Fiore	2017		Observational	125		125
INT 0031/05	EpSSG RMS 2005 A protocol for non metastatic Rhabdomyosarcoma	A. Ferrari	2005		III	125	Closed accrual	
INT 0169/17	Anthracycline, Gemcitabine and Pazopanib in epithelioid sarcoma: a retrospective multi-institutional case series	S. Stacchiotti	2017	01/10/2017	Observational	115		Closed accrual
INT 0197/16	"Multicenter retrospective observational chart review on treatment management of Soft Tissue Sarcoma Patients Treated by Surgery with or without Perioperative Treatment"	A. Gronchi	2017		Observational	98		98
INT 0188/13	Overcoming anti-angiogenetic therapy resistance in selected sarcomas	S. Pilotti	2014	31/12/2017	Observational	89	54	Closed accrual
INT 0013/14	Long term morbidity and quality of life after multivisceral resection for primary retroperitoneal soft tissue sarcomas: a prospective observational study	M. Fiore	2014		Observational	65	Closed accrual	
INT 0066/10	Localized high-risk soft tissue sarcomas of the extremities and trunk wall in adults: an integrating approach comprising standard vs histotype-tailored neoadjuvant chemotherapy	A. Gronchi	2011		II	63	4	1
INT 0073/11	ABCB1/P-glycoprotein expression as factor for the biologic stratification of the metastatic osteosarcoma of the extremities: a prospective study	R. Bertulli	2012		II	54	10	10
INT 0201/16	REtroperitoneal SArcoma Registry (RESAR): prospective collection of primary retroperitoneal sarcoma patient's data, radiological and pathological material for the TransAtlantic Retroperitoneal Sarcoma Working Group	A. Gronchi	2017		Observational	54		54
INT 0194/15	Targeting the osteosarcoma-associated immune environment	C. Chiodoni	2016		Observational	53	5	48



SCIENTIFIC REPORT 2016-2017

SARCOMAS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0059/11	STRASS A phase III randomized STudy of preoperative RAdiotherapy plus Surgery versus surgery alone for patients with Retroperitoneal Sarcoma (RPS)	A. Gronchi	2012		Non applicable	50	14	Closed accrual
INT 0044/10	Phase II study on imatinib in combination with RAD001 in advanced chordoma	S. Stacchiotti	2011		II	44		
INT 0054/13	Observational study of whole-transcriptome and whole-exome sequencing analysis in tumor samples of extraskeletal myxoid chondrosarcoma, malignant myoepithelioma, and dermatofibrosarcoma protuberans with or without fibrosarcomatous component	S. Stacchiotti	2013		Observational	40	Closed accrual	
INT 0091/16	Application of a perioperative nutritional and hemodynamic protocol in patients with retroperitoneal sarcomas. A feasibility study	P. Previtali	2016		-	37	16	Closed accrual
INT 0111/16	Trabectedin in Soft Tissue Sarcomas. A retrospective analysis	P. G. Casali	2016	20/12/2017	Observational	36		Closed accrual
INT 0062/08	Open label, multi-center, phase II study Denosumab in subject with giant cell tumor of bone	P. G. Casali	2008		II	26	Closed accrual	
INT 0131/16	Dedifferentiated retroperitoneal liposarcoma: developing in vitro and in vivo models to understand tumor biology and pre-clinically evaluate novel therapeutic strategies	C. Colombo	2016		Observational	21	6	15
INT 0093/14	A Phase II Open-Label Trial of Pazopanib Administered as a Single Agent in Patients with Unresectable or Metastatic Solitary Fibrous Tumor (SFT) and Extraskeletal Myxoid Chondrosarcoma (EMC)	S. Stacchiotti	2014		II	19	6	2
INT 0007/14	Phase II study of Axitinib in advanced solitary fibrous tumor	S. Stacchiotti	2015		II	18	2	Closed accrual
INT 0189/15	A Phase II, Multicenter Study of the EZH2 Inhibitor Tazemetostat in Adult Subjects with INI1-Negative Tumors or Relapsed/Refractory Synovial Sarcoma	S. Stacchiotti	2016		II	15	9	6
INT 0182/13	High throughput genome study to identify predictors of aggressiveness in patients with sporadic desmoid tumor who undergo a wait and see approach	C. Colombo	2013	01/11/2017	Observational	15	5	Closed accrual
INT 0031/03	EUROpean Bone Over 40 Sarcoma Study. A European treatment protocol for bone-sarcoma in patients older than 40 years	P. G. Casali	2003		II/III	14		

ONGOING CLINICAL STUDIES 2016-2017

SARCOMAS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0028/11	Rabdomiosarcoma of adults. An observational prospective study	R. Bertulli	2011		Observational	13	2	0
INT 0062/15	A double-blind, Randomized, Placebo-controlled Phase III Study of Orally Administered PLX3397 in Subjects with Pigmented Villonodular Synovitis or Giant Cell Tumor of the Tendon Sheath	S. Stacchiotti	2016		III	11	Closed accrual	
INT 0075/14	Randomized phase II trial of Cabazitaxel or prolonged infusional Ifosfamide in metastatic or inoperable locally advanced dedifferentiated liposarcoma	P. G. Casali	2017		II	9		9
INT 0110/15	Phase II study on Regorafenib in advanced Solitary Fibrous Tumor	S. Stacchiotti	2015		III	8	4	3
INT 0135/16	Endometrial stromal tumors: an observational study	P. G. Casali	2017		Observational	8		8
INT 0078/09	A phase II randomized - non comparative - study onthe activity of Trabectedin or Gemcitabine + Docetaxel in metastatic or locally relapsed uterine leiomyosarcoma pretreated with conventional chemotherapy	P. G. Casali	2010		II	8	Closed accrual	
INT 0114/13	Patients with atypical osteosarcoma and/or are not elegible in other ISG clinical trials	R. Bertulli	2013		Observational	7	0	2
INT 0064/15	Phase I/II prospective trial, multicenter, open label, exploring the combination of Trabectedin plus RAdiotherapy in Soft Tissue Sarcoma patients	A. Gronchi	2016		I/II	7	2	5
INT 0023/15	Evaluation of MGMT promoter methylation status and clinical benefit from therapy based on temozolomide for advanced Ewing's sarcoma	R. Bertulli	2015		Observational	6	0	0
INT 0139/17	Rare soft tissue sarcoma histologies: developing in vitro and in vivo models to understand tumor biology and pre-clinically evaluate novel therapeutic strategies	S. Stacchiotti	2017		Observational	6		6
INT 0170/17	Prospective study of the expression of tyrosin-kinase receptor chimeric proteins TrkA, Trkb, TrkC, ALK, and ROS1 in adult soft tissue sarcoma cases by immunohistochemistry and next generation sequencing (NGS), and correlation with clinico-pathologic data at onset and during follow-up	P. Collini	2017		Observational	5		5



SCIENTIFIC REPORT 2016-2017

SARCOMAS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0116/15	A multicenter randomized, open-label phase II/III study, to compare the efficacy of NBTXR3, implanted as intratumor injection and activated by radiotherapy, versus radiotherapy alone in patients with locally advanced soft tissue sarcoma of the extremity and trunk wall	A. Gronchi	2016		-	5	4	Closed accrual
INT 0124/16	Protocol I5B-MC-JGDM: A Phase Ib Trial to Assess the Modulation of Biological Markers in Patients with Potentially Resectable Soft Tissue Sarcoma Treated with Olaratumab Monotherapy Followed by Olaratumab plus Doxorubicin Combination Therapy	S. Stacchiotti	2017		I	3		Closed accrual
INT 0005/11	Translational study on modulation of gene transcription induced by Trabectedin in patients with myxoid/round cell liposarcoma	P. G. Casali	2011		Observational	2	0	0
INT 0073/17	Epithelioid sarcoma. An observational study	P. G. Casali	2017		Observational	1		1
INT 0102/16	Phase II, single arm, non-randomized and multicenter clinical trial of Regorafenib as a single agent in the first-line setting for patients with metastatic and/or unresectable KIT/PDGFR Wild Type GIST	P. G. Casali	2017		II	1		1
INT 0137/15	A Randomized, Double-Blind, Placebo-Controlled, Phase III Trial of Doxorubicin plus Olaratumab versus Doxorubicin plus Placebo in Patients with Advanced or Metastatic Soft Tissue Sarcoma	P. G. Casali	2016		III	1	Closed accrual	
INT 0019/11	A randomized, open label, multicenter, phase III study to compare the efficacy and safety of Eribulin with Dacarbazine in subjects with soft tissue sarcoma	P. G. Casali	2011	14/09/2016	III	4		
INT 0025/16	Observational retrospective study on the natural history of patients affected by primary, localized dermatofibrosarcoma protuberans (DFSP) treated with surgical resection	S. Stacchiotti	2016	31/05/2016	Observational	263	Closed accrual	
INT 0039/16	Outcome after surgical resection of recurrent retroperitoneal sarcomas: retrospective multicentric study	A. Gronchi	2016	10/07/2016	Observational	127	Closed accrual	
INT 0064/16	Retrospective study of a series of patients with epithelioid angiosarcoma of the thyroid gland without distant metastases at diagnosis treated with surgery, chemotherapy and radiation therapy: clinicopathologic features at diagnosis and follow-up, and correlation with biologic behaviour	P. Collini	2016	15/09/2016	Observational	6	Closed accrual	

ONGOING CLINICAL STUDIES 2016-2017

SARCOMAS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0017/14	Assessment of BoNT/A effects on muscle cells and fibroblasts	C. Colombo	2014	42522	-	8	Closed accrual	

URINARY APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0062/12	A randomized, open label, multicenter phase II study, to evaluate the efficacy of Sorafenib in patients with advanced Renal Cell Carcinoma (RCC) after a radical resection of the metastases.	G. Procopio	2012		II	43	6	7
INT 0065/12	A Prospective Observational Study of Real World Treatment Patterns and Treatment Outcomes in Patients with Advanced or Metastatic Renal Cell Carcinoma Receiving Pazopanib	G. Procopio	2012	03/07/2017	Observational	40		
INT 0101/16	PURE-01 – An open label, single-arm, phase II study of neoadjuvant pembrolizumab (MK-3475) before cystectomy for patients with muscle-invasive urothelial bladder cancer	A. Necchi	2017		II	32		32
INT 0146/14	Prospective translational study investigating possible molecular predictors of resistance to first-line pazopanib in metastatic renal cell carcinoma for future research	G. Procopio	2015		-	27	20	Closed accrual
INT 0059/14	A phase II, multicenter, single-arm study of Atezolizumab in patients with locally advanced or metastatic urothelial bladder cancer	A. Necchi	2014		II	25		
INT 0026/16	Phase III, Randomized, Controlled, Multi-Center, Open-Label Study to Compare Tivozanib Hydrochloride to Sorafenib in Subjects With Refractory Advanced Renal Cell Carcinoma	E. Verzoni	2016		III	25	16	Closed accrual
INT 0004/14	A Phase III trial to evaluate the efficacy of orasol plus mouthwash associated with oral hygiene standard (vs oral hygiene standard) in the prevention of stomatitis of everolimus in patients with advanced renal cell carcinoma (everolimus-induced STOMatitis Prevention trial)	G. Procopio	2014	18/04/2017	-	20	5	Closed accrual



SCIENTIFIC REPORT 2016-2017

URINARY APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0017/15	A phase II single arm clinical trial of nivolumab (BMS-936558) in subjects with metastatic or unresectable urothelial cancer who have progressed or recurred following treatment with a platinum agent	A. Necchi	2015		II	19		
INT 0047/16	A Phase III, Randomized, Double-Blind, Placebo Controlled Study of Ramucirumab plus Docetaxel Versus Placebo plus Docetaxel in Patients with Locally Advanced or Unresectable or Metastatic Urothelial Carcinoma Who Progressed Following Platinum-Based Therapy	A. Necchi	2016		III	19	18	Closed accrual
INT 0009/11	A randomized, double blind, placebo-controlled phase III study to evaluate the efficacy and safety of pazopanib as adjuvant therapy for subjects with localized or locally advanced RCC following nephrectomy	G. Procopio	2011		III	18		
INT 0094/14	Activity and safety of third line tyrosin kinase inhibitor (TKI) after 2 tyrosin kinase inhibitors(TKIs) in patients with metastatic renal cell carcinoma (mRCC) (Tokio Study)	G. Procopio	2014	08/11/2017	II	17	8	Closed accrual
INT 0046/14	Activity and safety of second line Sorafenib After Pazopanib in patients with metastatic renal cell carcinoma (SOAP Study)	G. Procopio	2014	08/11/2017	II	16	3	Closed accrual
INT 0017/17	A phase III, multicenter, randomized, placebo-controlled, double-blind study of atezolizumab (anti-PD-L1 antibody) as adjuvant therapy in patients with renal cell carcinoma at high risk of developing metastasis following nephrectomy	G. Procopio	2017		III	16		16
INT 0026/17	A Phase II, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants with Advanced Renal Cell Carcinoma	G. Procopio	2017		II	14		Closed accrual
INT 0108/12	A Randomized, Open-Label, Phase III Study of BMS-936558 vs. Everolimus in Subjects with Advanced or Metastatic Clear-Cell Renal Cell Carcinoma Who Have Received Prior Anti-Angiogenic Therapy	G. Procopio	2013		III	14		
INT 0190/14	A phase III, open-label, multicenter, randomized study to investigate the efficacy and safety of MPDL3280A (anti-PD-L1 antibody) compared with chemotherapy in patients with locally advanced or metastatic urothelial bladder cancer after failure with platinum-containing chemotherapy	A. Necchi	2015		III	14		Closed accrual

ONGOING CLINICAL STUDIES 2016-2017

URINARY APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0075/15	Targeted Therapy With or Without Nephrectomy in Metastatic Renal Cell Carcinoma: Liquid Biopsy for Biomarkers Discovery	G. Procopio	2015		III	13	8	3
INT 0189/14	An open label, randomized, phase II study of Paclitaxel and Panitumumab compared to Paclitaxel alone in patients with relapsed or refractory urothelial cancer	A. Necchi	2015		II	13	8	0
INT 0133/14	A Phase III Randomized Clinical Trial of Pembrolizumab (MK-3475) versus Paclitaxel or Vinflunine in Subjects with Recurrent or Progressive Metastatic Urothelial Cancer	A. Necchi	2014		III	12		
INT 0171/14	A Phase III, Randomized, Open-Label Study of Nivolumab Combined with Ipilimumab Versus Sunitinib Monotherapy in Subjects with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma	G. Procopio	2015		III	10		
INT 0002/17	An open label, single arm, multicenter, safety study of atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract	A. Necchi	2017		III	9		9
INT 0098/13	A phase IB/II study of GDC-0068 or GDC-0980 with abiraterone acetate versus abiraterone acetate in patients with castration-resistant prostate cancer previously treated with docetaxel-based chemotherapy	G. Procopio	2013	04/01/2017	I/II	8		
INT 0143/15	Axitinib In ADvanced / Metastatic Renal Cell CarcinOma - A Non-Interventional Study of Real World Treatment Outcomes in Patients Receiving 2nd Line Axitinib after 1st Line Sunitinib (ADONIS)	G. Procopio	2017		Observational	7		Closed accrual
INT 0182/16	A phase III, multinational, randomized, open-label, parallel-arm study of Avelumab (MSB0010718C) in combination with Axitinib (Inlyta®) versus Sunitinib (Sutent®) monotherapy in the first-line treatment of patients with advanced renal cell carcinoma	E. Verzoni	2017		III	7		Closed accrual
INT 0067/16	A Phase III Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab versus Placebo in Subjects with High Risk Invasive Urothelial Carcinoma	A. Necchi	2016		III	6	4	2
INT 0053/07	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	G. Procopio	2008	20/01/2017	III	6		



SCIENTIFIC REPORT 2016-2017

URINARY APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0090/16	A phase III, multicenter, multinational, randomized, open-label, parallel-arm study of Avelumab (MSB0010718C) plus best supportive care versus best supportive care alone as a maintenance treatment in patients with locally advanced or metastatic urothelial cancer whose disease did not progress after completion of first-line platinum-containing chemotherapy	A. Necchi	2017		III	5		5
INT 0122/16	A Phase III, multicenter, randomized, placebo-controlled study of atezolizumab (anti-PD-L1 antibody) as monotherapy and in combination with platinum-based chemotherapy in patients with untreated locally advanced or metastatic urothelial carcinoma	A. Necchi	2017		III	5		5
INT 0131/17	Phase III, Open-label, Randomized Study of Nivolumab Combined with piliimumab versus Standard of Care Chemotherapy in Participants with Previously Untreated Unresectable or Metastatic Urothelial Cancer	A. Necchi	2017		III	5		5
INT 0045/16	A Phase II Clinical Trial to Study the Efficacy and Safety of Pembrolizumab (MK-3475) in Subjects with High Risk Non-muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus Calmette-Guerin (BCG) Therapy	A. Necchi	2016		II	5	3	2
INT 0025/14	A Phase III study of Paclitaxel and Ifosfamide plus either Cisplatin or Carboplatin for patients with metastatic non-transitional cell carcinoma of the bladder and the urinary tract	A. Necchi	2014		II	2	0	0
INT 0115/15	Active surveillance of kidney tumors T1a equal or smaller than 2 cm	R. Salvioni	2016		-	1		1
INT 0110/17	Nivolumab plus Stereotactic Body Radiotherapy (SBRT) in II and III line of Patients With Metastatic Renal Cell Carcinoma (mRCC)	G. Procopio	2017		II	1		1
INT 0052/10	A phase II study of neoadjuvant Cisplatin and Gemcitabine plus Sorafenib for patients with transitional cell carcinoma of the bladder	R. Salvioni	2011	31/12/2016	II	45	Closed accrual	
INT 0046/12	Evaluation of microRNA expression in prostate cancer for the identification of novel diagnostic and prognostic markers	N. Zaffaroni	2012	31/12/2016	Observational	17		

ONGOING CLINICAL STUDIES 2016-2017

SCIENTIFIC REPORT 2016-2017

URINARY APPARATUS

Study Code	Title	Coordinator	Activated	Closed	Phase	Total patients	Patients enrolled in 2016	Patients enrolled in 2017
INT 0171/13	A re-treatment safety study of radium-223 dichloride in subjects with castration-resistant prostate cancer with bone metastases who received an initial course of six doses of radium-223 dichloride 50 kBq/kg every four weeks	G. Procopio	2014	20/01/2016	II	2		
INT 0049/14	Advanced urothelial cancer of the bladder, urethra, or the upper urinary tract who are resistant to platinum-based therapy	A. Necchi	2014	08/09/2016	II	22		
INT 0115/14	Feasibility of a home-based Pre-habilitation Program for Patients with Muscle Invasive Bladder Cancer, submitted to Neo-Adjuvant Chemotherapy and candidates to Radical Cystectomy with Urinary Reconstruction	M. Maffezzini	2014	25/08/2016	-	21	Closed accrual	
INT 0150/15	Surgery after systemic therapy for clinically node-positive metastatic urothelial bladder cancer: an international collaboration	A. Necchi	2016	31/12/2016	Observational	35	Closed accrual	
INT 0010/11	Biotech of prostate cancer	N. Zaffaroni	2011		-	228	12	67
INT 0136/17	Clinical outcomes of advanced urothelial carcinoma patients following disease progression to programmed death (PD)-1 or PD-ligand (L)-1 inhibitors	A. Necchi	2017		-	96		96





ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

AIL - Italian Association against leukemia-lymphoma and myeloma ONLUS

- 2991** Application of next generation sequencing in the diagnosis and molecular characterization of lymphoproliferative disorders.
- 2980** Myeloma Project

AIOM - Italian Association of Medical Oncology

- 2721** Gene expression profiling of HER2 and Hormone Receptor positive breast cancer fit to individualized HER2 targeted treatment

AIRC - Association for Italian Cancer Research

- 1478** Cell therapy with TRAIL-armed, genetically engineered or phenotypically redirected, effectors
- 1689** Tumor-Microenvironment related changes as new tools for early detection and assessment of high-risk \disease (Cod. 12162)
- 1686** Hypercoagulation screening as an innovative tool for risk assessment, early diagnosis and prognosis in cancer
- 1778** Lifestyle and Breast Cancer Recurrences: The DIANA-5 Trial
- 1783** Involvement of microRNAs in Breast Cancer Driving Pathways: from Biology to possible Therapies
- 1917** Statistical Tools for Prognosis and Prediction in Cancer: Assessments and Application to a Sarcoma Case Series
- 1920** Regulation of Myeloid Cells Homeostasis by ECM Proteins: implication for autoimmunity and myeloid malignancies
- 1939** Effects of high Intra-abdominal pressure on tissue diffusion and pharmacokinetics of cisplatin during HIPEC
- 1940** Identification of a molecular predictor of response to Cetuximab based on a phase II trial in recurrent/metastatic HNSCC
- 1943** Overcoming Anti-Angiogenic Therapy Resistance in Selected Sarcomas
- 1947** Diagnostic an therapeutic potential of microRNAs in Lung Cancer
- 1948** Understanding the biological basis of chemorefractoriness in peripheral T-cell Lymphoma to develop novel treatments
- 1954** Circulating miRNAs to predict outcome and to guide treatment of breast cancer patients on preoperative systemic therapy
- 1955** Extracellular Matrix-Mast cells interplay molds nascent tumor microenvironment
- 1960** Retrospective and prospective study of late radiation damages after focal radiotherapy for childhood brain tumors
- 1961** Validation of HSP105 as novel biotarget in human non-Hodgkin lymphomas
- 1962** Role of acidity in tumor immunity
- 2139** Role of germline and somatic DNA change in modulating the survival of patients with lung adenocarcinoma

ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

AIRC - Association for Italian Cancer Research

- 2233** Cancer Therapy trough TLR-induced local innate immunity activation and block of immune checkpoints or suppressive cells
- 2238** Targeted therapy with or without nephrectomy in metastatic renal cell carcinoma: liquid biopsy for biomarkers discovery
- 2239** Expanding the repertoire of genetic factors associated with hereditary susceptibility to breast cancer
- 2242** Study of HER2 addiction-related features implicated in trastuzumab benefit
- 2244** Modelling toxicity after high dose RT for prostate cancer: validating clinical, dosimetric and molecular factors
- 2245** Dissecting the role of microRNAs in the radiation response of human prostate cancer
- 2246** Translational research to a practice changing global prospective study of androgen deprivation in salivary gland cancers
- 2251** Interaction between clinical and genetic factors in modulation of opioid analgesia and side effects in cancer pain
- 2252** Interfering with PH regulators as a immunomodulating therapeutic strategy
- 2257** Identification of regulators of the alternative lengthening of telomeres in human cancer cells
- 2259** Targeting KRAS mutations in NSCLC trough LKB1 co-vulnerability
- 2261** Epistasis in lung tumorigenesis: an experimental approach to discover interacting gene networks relevant to human cancer
- 2262** Targeting melanoma dedifferentiation and EMT to promote immunogenicity
- 2263** Genetic profile and patient-derived xenografts (PDX) for innovative management of screening-detected lung cancer
- 2264** Interference with Akt-mediated drug-resistance mechanisms to target aggressive ovarian carcinoma
- 2418** Immune profiles of response and mechanisms of resistance to immune checkpoint blockade in solid tumors.
- 2421** Functional genomic and transcriptomic analysis of drug-resistant myeloma.
- 2424** Translational correlates to ongoing phase II studies on paranasal sinus cancer treated with a multimodal approach.
- 2427** Targeting the osteosarcoma-associated immune environment.
- 2428** Monitoring disease progression in triple negative breast cancers by profiling liquid biopsies and tumor lesions.
- 2441** Integrated genomic, epigenomic and metabolic approaches to overcome ovarian cancer early relapse and chemoresistance.
- 2442** LIFESTYLE AND THE PENETRANCE OF BRCA MUTATION.
- 2443** Role of d16HER2 splice variant in breast cancer aggressiveness as a function of addiction to HER2 signaling.
- 2444** Exploration of CD30-associated immunosuppression signals in the sentinel node of melanoma patients.
- 2445** miRNA based therapeutics to target pro-tumorigenic potential of stromal fibroblasts in lung cancer.
- 2448** Role of inorganic xenoestrogens and their binding proteins in risk of developing breast cancer subtypes.
- 2782** Carbon ions boost followed by pelvic photon radiotherapy for high risk prostate cancer
- 2862** Learning the lesson of tamoxifen metabolites: design of multi-targeted human aromatase and estrogen receptor modulators



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AIRC - Association for Italian Cancer Research

- 2741** Cross-talk between tumor cells and adipocytes as a trigger for breast cancer progression
- 2743** Functional characterization and therapeutic potential of circulating exosome-associated miRNAs in lung cancer
- 2747** Bevacizumab in ovarian cancer: identification of molecular signatures driving patients selection
- 2749** Dissection of thyroid tumor dependency on COPZ1 and MASTL activity: an approach to identify novel therapeutic targets
- 2753** Pseudomyxoma peritonei: optimizing treatment by exploring the connections between oncogene mutations and inflammation
- 2754** Radiogenomics Framework for Non-Invasive Personalized Medicine in Head and Neck Cancer
- 2756** Extracellular matrix regulation of my

AIRC - Association for Italian Cancer Research FIRC- Foundation for Italian Cancer Research

- 2119** DELTA16HER2 involvement in tumor-initiating cells of HER2-positive breast carcinomas. (Fellowship)
- 2371** Biological and Clinical Significance of Circulating Tumor Cells in Breast Cancer. (Fellowship)
- 2373** Cross-influence between extracellular matrix and differentiated versus undifferentiated breast carcinoma cells. (Fellowship)
- 2545** Pancreatic cancer etiology: integrating dietary aspects and medical history in a global consortium (PanC4). (Fellowship)
- 2614** A novel human skin organoid model to investigate myeloid cell-tumor cell interactions in the melanoma microenvironment. (Fellowship)
- 2553** Mechanisms of response and resistance to immune checkpoint blockade therapy in melanoma. (Fellowship)
- 2949** Characterization of SIX and miRNA processor genes mutations in Wilms tumor recurrences. (Fellowship)
- 2955** Identification of plasma microRNA biomarkers during breast cancer development. (Fellowship)

Bianca Garavaglia Association

- 2467** Radiological diagnostic of CNS cancers
- 2468** "Liquoral diagnostic of CNS cancers"
- 2470** Endocrinology of CNS cancers
- 2471** Serum biomarkers in the brain bridge intrinsic glioma
- 2472** Therapeutic trials
- 2473** Pediatric radiotherapy
- 2474** Clinical study on renal cancer in pediatric ages
- 2476** Histopathology of renal cancers

ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

Bianca Garavaglia Association

- 2477** Bio-molecular characterization of Wilms cancer
- 2478** Second cancers/fertility/cardiological sequelae
- 2479** Study on the role of breast cancer predisposition genes in the development of pediatric cancers
- 2480** Identification of potential targets for targeted cell therapy, and expression of immune-inhibitory molecules in the tumor microenvironment of patients with neuroblastoma
- 2481** New drugs in pediatric cancer treatment
- 2482** Molecular study of child and adolescent sarcomas for the identification of new drugs
- 2483** Strategies of heparanase/ heparan sulfate inhibition, a new molecular target for the therapy of pediatric sarcomas
- 2484** The youth project
- 2485** The sport project: in-hospital physical activity with sport instructors to encourage children and adolescents with cancer to play sport
- 2486** Physical and psychological rehabilitation of patients with bone tumors.
- 2487** Outsourcing projects
- 2488** Psychodynamic and neuropsychiatric activity
- 2489** Integration of nursing activity

Patrizia Revello Association

- 3003** Annual training program focused on the identification of new therapeutic targets and the development of new pharmacological strategies for triple negative breast cancer.

Italian Association GIST Onlus

- 2793** Indirect donation for the perspective observational study: "Gastrointestinal stromal tumors (GISTS)".

Marta Nurizzo Association

- 2568** Project called: Identification of germline mutations associated with lung cancer in non smoking patients

Local health authority

- 2110** Pavia Province Cancer Registry
- 2981** Open Registry for the creation of the regional Cancer Registry
- 2982** Open Registry for the creation of the regional Cancer Registry



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Local health authority

- 2985** Open Registry for the creation of the regional Cancer Registry

Barilla S.p.A.

- 2859** A contract of scientific collaboration with Barilla G. and R. Fratelli S.P.A. for the execution of the activities linked to an European multicentre project (EPIC ITALIA PROJECT).

European Commission

- 1597** (EUROSARC) European clinical trials in rare sarcomas within an integrated translational trial network
- 1578** IMMUNOCAN - Toward enhancing activities of European institutions in the FDUSCC-IM cancer research joint institute in China
- 1452** Determinants of eating behaviour in European children, adolescents and their parents (I.Family)
- 1574** RARECAREN (rare cancers information network)
- 2097** BENCH-CAN: Benchmarking comprehensive cancer care that provides interdisciplinary treatment for patients, and yield examples of best practice in comprehensive cancer care
- 1775** Randomized controlled trial of metformin and dietary restriction to prevent age-related morbid events in people with metabolic syndrome (MEMEME)
- 1895** Validating predictive models and biomarkers of radiotherapy toxicity to reduce side-effects and improve quality-of-life in cancer survivors (REQUITE)
- 1898** Immunostimulatory Agonist Antibodies for Cancer Therapy (IACT)
- 2168** European guide on quality improvement in comprehensive cancer control (CANCON)
- 1927** European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment (ExPo-r-NeT)
- 2398** TackSHS. Tackling secondhand tobacco smoke and e-cigarette emissions: exposure assessment, novel interventions, impact on lung diseases and economic burden in diverse European populations.
- 2533** BD2DECIDE. Big Data and models for personalized Head and Neck Cancer Decision Support
- 2795** ICARO: Colloidal Inorganic Nanostructures for Radiotherapy and Chemotherapy
- 2567** PRECIOUS. Scaling-up biodegradable nanomedicines for multimodal precision cancer immunotherapy
- 2792** JARC - Joint Action on rare cancers
- 2726** SPIDIA4P - SPIDIA for Personalized Medicine - Standardisation of generic Pre-analytical procedures for Invitro DIAgnostics for Personalized Medicine (CSA)
- 2796** ITCC Pediatric Preclinical POC Platform (ITCCP4)
- 2727** PAIN-NET- Pain networks from cells to patients

ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

Municipalities of Italy

- 2986** Evaluation on the analysis of the epidemiological, toxicological and health aspects liked to waste disposal activity in the controlled landfill "La Cornacchia", owned by the municipality of Maiolati Spontini (AN)

Cook Ireland Ltd

- 3099** Clinical impact of the needle aspiration in endoscopy using a standardized method of evaluation without a pathologist in the surgery room. (Fellowship)

FIRB (Fund for the Investments of Basic Research)

- 1549** Advanced nanosystems for a new molecular oncology (NEWTON) RBAP11BYNP_001

ARCO Foundation

- 2863** Pharmacodynamic analysis of angiogenesis-related factors during regorafenib therapy for metastatic colorectal cancer: the REGOLAND project.

Cariplo Foundation

- 2031** Contribution of T Memory Stem Cells to successful Immune Recovery in humans following Bone Marrow Transplantation
- 2066** Disease recurrence in epithelial ovarian cancer: deciphering miRNA-driven regulatory networks related to drug sensitivity/cellular plasticity and exploring nanomaterial-based targeted delivery of identified key molecules for therapeutic purposes
- 2068** Role of Tumor Microenvironment in Thyroid Carcinogenesis Onset and Progression: Thyroid Cell Cross-Talk with Macrophages
- 2511** Role and therapeutic potential of microRNAs in non small cell lung cancer (NSCLC)
- 2504** MicroRNAs in the regulation of melanoma cell apoptosis and their application for therapeutic strategies
- 2510** Dissecting the role of unexplored miR-205 host gene as long non-coding RNA in prostate basal cells: implications for cancer development

Giovanni Celeglin Foundation

- 2587** Characterization of a circulating miRNA signature in response to targeted therapy in Diffuse Intrinsic Pontine Glioma (DIPG) patients.

Guido Berlucchi Foundation

- 2290** Search for new predictors of response to erlotinib in patients with non-small cell lung cancer without EGFR mutations
- 2417** Mechanisms of response and resistance to PD-1 pathway blockade therapy in melanoma. (Fellowship)



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Italian Neuroblastoma Foundation

- 2387** Treatment of neuroblastoma patients with T lymphocytes genetically modified to express a GD2-specific chimeric antigen receptor (CAR) and a safety switch

Italo Monzino Foundation

- 2053** Identification and validation of new therapeutic targets and biomarkers in prostate cancer.
- 2789** "For a shared feeling"
- 2655** "Continuation of "PROCABIO" project"
- 2791** Continuation of "For a shared feeling" project

Michelangelo Foundation

- 2784** "Creation of vectors, production and purification of reagents on a antibody basis. (Fellowship)"

Pezcoller Foundation

- 2633** Relevance of HER2 addiction in breast tumor immune infiltration and benefit from trastuzumab treatment. (Fellowship)

Rocca Foundation

- 2619** Computerised database for the registration of all physical, physiological, spiritual and social symptoms of the patients and their relatives (purpose: to treat the complications of chemotherapy and radiotherapy).

5x1000 funds

- 1807** Innovative approaches in tumour diagnostic and therapy
- 1808** Multidisciplinary disease-oriented approach
- 2140** "The genetics of stem cells in breast cancer: common ancestors or progenitors specific clone?"
- 2315** Development of the institutional breast cancer clinical registry.
- 2316** The Research Biobank
- 2318** EPIC Study - Italy
- 2319** Optimization of the management of research projects.
- 2144** Circulating microRNA as markers for monitoring the biological effect and clinical efficacy of neoadjuvant treatment in patients with HER2-positive breast cancer: a retrospective-prospective study in the international multicenter clinical protocol NEOALLTO

ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

5x1000 funds

- 2454** Coordinate the planning and management of clinical trials and optimize the use of dedicated resources through the Clinical Trials Center
- 2455** Gynadart - Adaptive Brachytherapy guided by MRI images in the exclusive treatment of locally advanced carcinoma of the cervix according to European standards of excellence: study of the quality of the treatment in terms of applicability and clinical and dosimetric outcome.
- 2456** SINTART 1-2 - Multidisciplinary approach for sinonal tumors with severe prognosis: a phase II study of the integration of surgery, chemotherapy, photons and heavy ions for a more effective and less toxic treatment in unresectable or inoperable patients.
- 2457** Institutional Tumour Registry
- 2459** Study on the clinical relevance of gene variants BRCA1/ BRCA2 identified in individuals at risk for hereditary breast and ovarian cancer.
- 2460** MicroRNA profiling and response to HER2 targeting
- 2461** Rare Cancers in Europe and Italy
- 2462** Multiparametric molecular characterization of human solid tumors in adults (lung, breast, pancreas, prostate, urothelium and soft tissue) and children for the identification of prognostic and predictive factors for clinical use.
- 2458** Identification of a molecular marker capable of identifying patients with breast cancer who benefit from targeted treatment for HER2.

Umberto Veronesi Foundation

- 2589** Role of PD-1/PD-L1 axis in regulating innate immune response in the tumor microenvironment. (Fellowship)
- 2594** NEXT GENERATION CLINICAL TRIAL: A TARGETED SEQUENCING-BASED UMBRELLA STUDY TO ADDRESS PATIENTS TO PERSONALIZED UROTHELIAL CANCER THERAPY. (Fellowship)
- 2607** Effects of tumor-secreted miR-9 on human fibroblast. (Fellowship)
- 2597** Development of novel therapeutic strategies for triple-negative breast cancer based on the interference with the epigenetic control of survivin expression and the intracellular distribution of the protein. (Fellowship)
- 2600** Lung metastasectomy for sarcomas in pediatric population: searching for biologic profiles that predict long-term survival. (Fellowship)
- 2601** Next generation sequencing of teratoma with malignant transformation (TMT) to uncover potentially meaningful insights into the biology of germ cell tumors. (Fellowship)
- 2598** Mast cells tip the balance between adenocarcinoma and neuroendocrine prostate cancer. (Fellowship)
- 2605** Characterization of tumor-suppressor activity of mir-486-5p in lung tumorigenesis. (Fellowship)
- 2608** Unveiling the role of COPZ1 in thyroid carcinoma: new potential therapeutic target? (Fellowship)
- 2824** Elucidating the mechanisms of DNA damage response activation in peripheral T cell lymphomas to develop novel therapies. (Fellowship)
- 2825** Identification of gene and miRNA expression profiles associated with radioiodine resistance in papillary thyroid carcinoma. (Fellowship)



SCIENTIFIC REPORT 2016-2017

Umberto Veronesi Foundation

- 2821** Read-through transcripts in normal lung and in lung adenocarcinoma: molecular origins, biological functions, and clinical relevance. (Fellowship)
- 2819** MiR-302b as adjuvant therapeutic tool to improve chemotherapy efficacy in human triple negative breast cancer. (Fellowship)
- 2816** Targeting lung metastasis initiating cells through a novel CXCR4-based combination strategy and monitoring treatment efficacy with liquid biopsies. (Fellowship)
- 2817** TLR3 as a potential target for local therapy in lung cancer. (Fellowship)
- 2818** Recovery of effective anti-tumor immunity in pediatric cancer. Preclinical evidences. (Fellowship)

INT - Call for Research Value

- 2923** MICRObiota, infLammatory Environment, clinicAl and Radiomic features as predictors of Normal tissue response in radiotherapy for prostatE and head-and-neck canceR. (MICRO-LEARNER)
- 2928** Identification of head and neck cancer and HPV-related infections by profiling volatile organic compounds in exhaled breath.
- 2932** Molecular and phenotypic landscape of high-grade breast cancer (HGBC) tumor microenvironment: characterization and reconversion of the immunosuppressive tumor-surrounding stroma and cell compartments
- 2943** Targeting the inhibitor of apoptosis proteins (IAPs) as a novel strategy to hinder microenvironment-dependent cancer aggressiveness
- 2937** Adolescents and young adults with cancers in Italy. How to ensure access to the best care and quality of survival
- 2921** Reducing overtreatment of early stage ovarian cancer: strategies implementation by a miRNA-driven prognostic assessment

Italian League Against Cancer (LILT)

- 2627** The contribution for the year 2016 was aimed at: the renewal of 3 fellowships for biologists/biotechnologists; to support the research activities in oncology; to the reagents necessary for starting the projects.
- 2628** The contribution for the year 2016 was aimed at the renewal of the contract of 2 graduates in physics.
- 2629** "The contribution for the year 2016 was aimed at the renewal of the clinical and research project entitled "Quality of life in the oncological Institution"."
- 2630** The contribution for the year 2016 aimed at the renewal of the contract for a physician expert in oncological lymphology.
- 2631** Contribution for the year 2016 aimed at: an annual professional collaboration of a psychologist; two annual collaborations for the recreational/training activities; a professional collaboration of a pediatric oral surgeon and its consumables; the activities for the recreational support during the weekends, on public holidays, in the summer, and the additional consumables.
- 2785** Contribution for the renewal of the contract of a physician which will take care of the diagnostic activity in the Day Surgery Unit and prevention areas of LILT.
- 2786** Contribution for the renewal of a professional collaboration at the maxillofacial surgery Unit in the field of the clinical and outpatient activities, operating room and screening activities at the prevention areas of LILT.
- 2787** Contribution for the on-call project

ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

Italian League Against Cancer (LILT)

- 2788** Contribution aimed at a professional collaboration in the context of the tomosynthesis project.
- 2977** Contribution for the renewal of an annual contract for a breast surgeon in the context of the D.A.R.E. project.
- 2978** The allocation for the year 2016 aimed at a partial annual contract for a practitioner working in the "Prevention areas" of LILT.
- 2979** Contribution for the purchase of 15 folding wheelchairs for the project "Protected hospitality Fondazione INT"
- 2783** Connection between response to locoregional therapies and circulating gene transcripts in neuroendocrine neoplasms.
- 2851** Contribution demand, for the year 2017, for the costs of the bus rental during the Pope's visit.
- 2852** Contribution, for the year 2017, aimed at the renewal of a contract in the context of the clinical and research activities and outpatient and diagnostic surgery at the Day Surgery Unit and in the "Prevention areas" of LILT.
- 2853** Contribution, for the year 2017, aimed at the support of the clinical and research project "Quality of life in the oncological Institution" of the Clinical Psychology Unit.
- 2854** Contribution for the year 2017 aimed at the financing and continuation of the ongoing projects: contract for 2 biologists, lab reagents and training course/conventions.
- 2855** "Contribution for the year 2017 aimed at the renewal of a contract for a graduate in physics."
- 2858** Contribution for the year 2017 aimed at a professional collaboration of an ophthalmologist, 2 annual collaborations for ricreative-training activities, a professional collaboration for a pediatric oral surgeon, consumables and activities supporting the ricreatives in the weekends, on public holidays and in summer.
- 2860** The contribution for the year 2017 aimed at the renewal of the contract for a physician expert in oncological lymphology.
- 2861** Contribution demand, for the year 2017, for a contract of a dietitian for the evaluation of the nutritional status, food requirements, calorie and protein intake and nutritional counseling in collaboration with the Medical Oncology Unit.
- 3006** Contribution for the renewal of a professional collaboration contract at the Otorhinolaryngology Unit in the context of the clinical, outpatients, surgery and screening activities at the Prevention areas of LILT.
- 3195** "Allocation for the continuation of the professional collaboration of a radiation oncologist assigned to the AMARANTA project."

Ministry of Health (Applied Research)

- 1791** "Comparison on a population basis of the disease markers RF-2009-1529710"
- 1864** Allergic components in experimental multiple sclerosis: novel targets for immune intervention* GR-2009-1607206
- 1710** IL-6-related inflammation signatures as a predictive marker of recurrence in liver cancer patients RF-2010-2312620
- 1713** Early detection and treatment of recurrent, chemotherapy-resistant ovarian cancer stem cells by CPE peptide complexed superparamagnetic iron oxide nanoparticles (CPE-SPIONs) RF-2010-2313497
- 1750** Identification and functional validation of microRNA biomarkers in lung cancer RF-2010-2306232
- 1761** Involvement of microRNAs in triple negative breast cancer: from biology to possible therapeutic applications GR-2010-2319582
- 1762** A randomized controlled trial of diet and physical activity in BRCA mutation carriers GR-2010-2310116



SCIENTIFIC REPORT 2016-2017

Ministry of Health (Applied Research)

- 1765** Deleted in Breast Cancer 1, a new player in the DNA damage response GR-2010-2315822
- 2165** HPV positive oropharyngeal cancer: characterization of immunological and viral profiles, and their role in the response to treatment RF-2011-02351315
- 2164** The role of early systematic best palliative care versus on request palliative care consultation during standard oncologic treatment for patients with advanced gastric or pancreatic cancer: a randomized, controlled, multicenter trial - RF-2011-02350971
- 2163** Generating stem cell-like T cells to improve immune reconstitution and anti-tumor immunity GR-2011-02347324
- 2367** Exploitation of human NK cell-derived exosomes as cell-free support in tumor immunotherapy GR-2011-02351400
- 2172** Microrna in papillary thyroid carcinoma: pathways involved and possible prognostic and therapeutic impact RF-2013-02354985
- 2179** Towards precision medicine for patients with biliary tract cancers: tailored treatments based on the mutational profile detected on tumor lesions and monitored in liquid biopsies (circulating tumor cells, CTC, and circulating tumor DNA, ctDNA) RF-2013-02359692
- 2185** Selective axillary lymph node dissection vs complete axillary dissection: a randomised clinical trial to assess the prevention of lymphedema in breast cancer treatment RF-2013-02355260
- 2217** Dissecting the role of unexplored miR-205 host gene as a basal cell-specific long non-coding RNA in prostate cancer development GR-2013-02355625
- 2224** Neutrophil traps in leukemia: from triggers of disease progression to vehicle for new vaccines GR-2013-02355637
- 2231** Functional inhibition of HSP105 as a new therapeutic strategy for human aggressive B-cell non-Hodgkin lymphomas GR-2013-02355412
- 2192** Molecular characterization of pulmonary sarcomatoid carcinoma, a deadly subtype of lung cancer, for patient management RF-2013-02357982

Ministry of Health (TRANSCAN)

- 1880** (BIO RARE) K-RAS mutations and DNA repair function in NSCLC.
- 2131** DietINT - A randomized phase II study for tertiary prevention of squamocellular cancer of head and neck (SCCHN) with a dietary intervention
- 2134** HIGHCARE. High resolution project on prognosis and CARE of cancer patients.
- 2369** DIGEST - Impact of Dietary Intervention on Tumor immunity
- 2650** MICROTHER - Improving immunotherapy of solid tumors by targeting the immunosuppressive tumor microenvironment: from pre-clinical "proof-of-concept" to the development of phase I studies

Movember Foundation

- 2805** Movember GAP3 Studio Multicentrico Internazionale

ONGOING PROJECTS SUPPORTED BY CHARITIES, INTERNATIONAL AND NATIONAL ORGANIZATIONS 2016-2017

NIH - National Institute of Health

- 1873** Identifying non-coding RNAs for early detection and prevention of lung cancer
- 3169** Surveillance of Rare Cancers in the Surveillance, Epidemiology, and End Results (SEER) Program

Lombardy Region

- 2112** "Use of donors with HBSAG positive encephalic lesions, anti-HBCORE positive, or ANTI-HCV positive according to national guidelines: improvement of liver allocation through the collection and the evaluation of the patient's organ short, medium and long term - TRASPLANTS RESEARCH PROJECT YEAR 2011"

Lombardy Region, CARIPLO Foundation

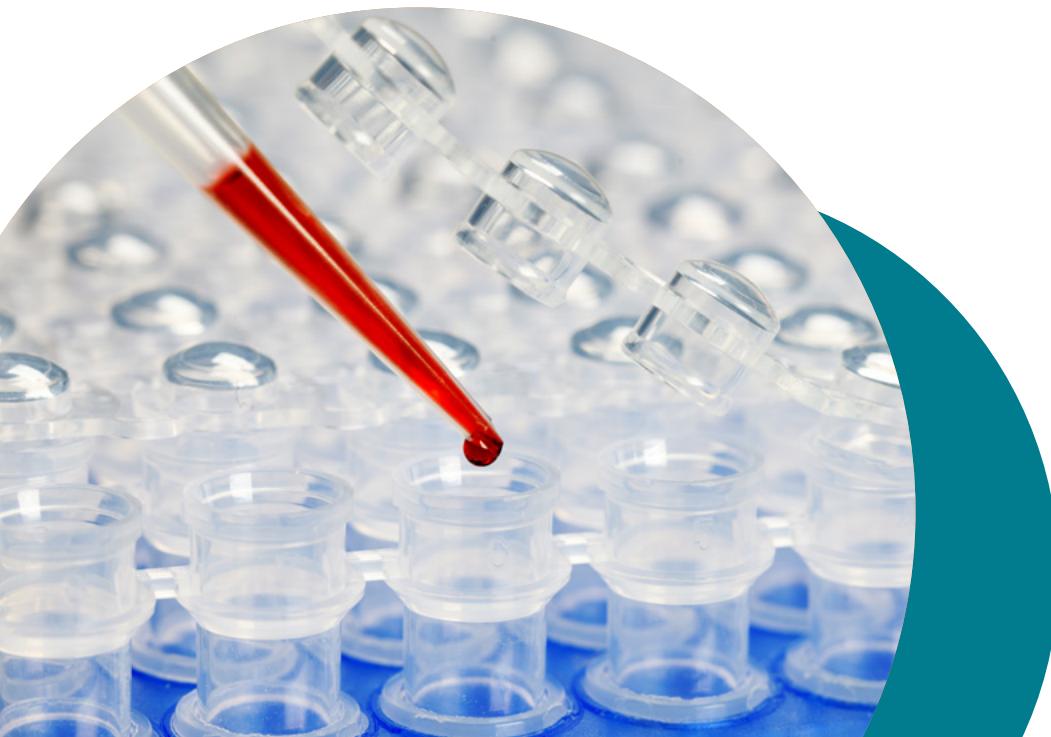
- 2733** KiSS1 and related network in the drug resistant and non small lung cancer metastasis.

Telethon

- 2313** Determinants of neurodegeneration in Ataxia Telangiectasia

University

- 2984** Open Registry for the development of the regional Cancer Registry







APPENDIX SCIENTIFIC REPORT

2016-2017

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