

Portfolio badań EORTC oraz status rekrutacji w Polsce

List of studies recruiting or under activation or recently closed for recruitment in Poland (*cut-off date: 26/04/2016*)

EORTC Study number (acronym)	Title/ description	Intergroup w/ non-EORTC groups? (Yes / No)	Date of activation at EORTC	Status in Poland	Participating Polish sites	Polish pts # / randomized pts # (sample size: EORTC/All groups)
BRAIN TUMOR GROUP (EORTC BTG)						
1410* ¹ (INTELLANCE 2)	ABT 414 alone or ABT 414 plus temozolomide versus lomustine or temozolomide for recurrent glioblastoma: a randomized phase II study of the EORTC Brain Tumor Group	Yes	14/01/2015	Recruiting	#551 (Gdansk)* ¹ #554 (Lodz)* ⁴	1/168 (All: 240)
BREAST GROUP (EORTC BCG)						
10085p (Prospective male BC)	Clinical and biological characterization of Male Breast Cancer: an international EORTC, BIG, TBCRC and NABCG intergroup study.	Yes	21/01/2014	Recruiting	#550 (Warsaw)* ⁴ #551 (Gdansk)* ⁴	4/198 (EORTC:30; All:200)
1307* ¹ (BRAVO)	A phase 3 randomized trial of Niraparib versus Physician's choice in patients with germline BRCA mutation and previously treated breast cancer.	Yes	31/10/2013	Recruiting	#9660 (Lodz)* ⁴ #9662 (Raciborz)* ⁴	1/151 (EORTC:50; All: 306)
1324* ¹ (OLYMPIA)	A randomised, double-blind, parallel group, placebo-controlled multi-centre Phase III study to assess the efficacy and safety of olaparib versus placebo as adjuvant treatment in patients with germline BRCA1/2 mutations and high risk HER2 negative primary breast cancer who have completed definitive local treatment and neoadjuvant or adjuvant chemotherapy.	Yes	22/04/2014	Recruiting	5800 (Poznan)* ¹ #550 (Warsaw)* ⁴	31/ 433 (EORTC:45; All: 7600)
1408 (AURORA)	Aiming to Understand the Molecular Aberrations in Metastatic Breast Cancer.	Yes	01/04/2014	Regulatory in process	#550(Warsaw)* ³ #5800 (Poznan)* ²	0/68 (EORTC:300; All: 1300)
1513 (PALLAS)	PALbociclib CoLlaborative Adjuvant Study: A randomized phase III trial of palbociclib with adjuvant endocrine therapy versus endocrine therapy alone for hormone receptor positive (HR+)/ human epidermal growth factor receptor 2 (HER2)-negative early breast Cancer	Yes	Regulatory in process	Regulatory in process	#550 (Warsaw)* ²	0/0 (All: 4600)
CANCER IN ELDERLY TASK FORCE (EORTC ETF)						
75111-10114	Pertuzumab + trastuzumab (PH) versus PH plus metronomic chemotherapy (PHM) in the elderly HER2+ metastatic breast cancer population who may continue on T-DM1 alone following disease progression while on PH/PHM: an open-label multicentre randomized phase II selection trial of the EORTC Elderly Task Force and Breast Cancer Group.	Yes	18/06/2013	Recruiting	#550 (Warsaw)* ⁴	2/75 (All: 80)

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ENDOCRINE TASK FORCE (EORTC ENTF)						
1209	A phase II study exploring the safety and efficacy of BIBF1120 as second line therapy for patients with either differentiated or medullary thyroid cancer progressing after first line therapy.	No	28/04/2014	Regulatory in process	#550 (Warsaw)* ³ #589 (Gliwice)* ³	0/70 (142)
LYMPHOMA GROUP (EORTC LYMG)						
1537	Phase II study in very early PET-response adapted targeted therapy for advanced Hodgkin lymphoma	No	Development		Sites selection	0/0 (150)
GASTROINTESTINAL TRACT CANCER GROUP (EORTC GTCG)						
40CRC (SPECTAcolor)	An EORTC prospective screening initiative for the determination of molecular parameters for advanced colorectal cancer	No	03/07/2013	On hold	#550 (Warsaw)* ⁴ #5800 (Poznan)* ⁴	0 / 803 (/)
1203 (INNOVATION)	Integration of trastuzumab, with or without pertuzumab, into perioperative chemotherapy of HER-2 positive stomach cancer: the INNOVATION-TRIAL	Yes	02/09/2015	Regulatory in process	#550 (Warsaw)* ²	0/6 (EORTC:105; All: 225)
1418	Nintedanib plus mFOLFOX6 for previously untreated metastatic esophagogastric adenocarcinoma: a randomized, placebo-controlled, double-blind phase II study.	No	Development		Sites selection	0 / 0 (240)
1527 (DREAM)	Diffusion-Weighted Magnetic Resonance Imaging Assessment of Liver Metastasis and Improve Surgery	Yes	Development		Sites selection	
GENITOURINARY CANCER GROUP (EORTC GUCG)						
1201* ¹ (PEACE-1)	A prospective randomised phase III study of androgen deprivation therapy with or without local radiotherapy with or without abiraterone acetate and prednisone in patient with metastatic hormone-naïve prostate cancer.	Yes	05/01/2015	Regulatory in process	#589 (Gliwice)* ¹ #9601 (Warsaw)* ¹ #9751 (Katowice)* ¹	0/18 (EORTC:300; All: 916)
1333 (PEACE III)	A randomized multicenter phase III trial, comparing enzalutamide vs combination of Ra223 and enzalutamide in asymptomatic or mildly symptomatic castration resistant prostate cancer patients metastatic to bone (mCRPC).	Yes	20/10/2015	Regulatory in process	#550 (Warsaw)* ³ #551 (Gdansk)* ²	0/12 (All: 560)
GYNECOLOGICAL CANCER GROUP (EORTC GCG)						
1528	A randomized phase II study of lenvatinib versus doxorubicin in second line advanced or recurrent endometrial cancer.	No	Development		#552 (Krakow)* ²	0/0 (/)

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HEAD & NECK CANCER GROUP (EORTC HNCG)						
1219 (DAHANCA-29)	A blind randomized multicenter study of accelerated fractionated chemo-radiotherapy with or without the hypoxic cell radiosensitizer nimorazole (Nimoral), using a 15-gene signature for hypoxia in the treatment of squamous cell carcinoma of the head and neck (DAHANCA-29)	Yes	27/05/2014	Regulatory in process	#5800 (Poznan)* ² #551 (Gdansk)* ²	0/108 (All: 640)
LUNG CANCER GROUP (EORTC LCG)						
08111* ¹ (ETOP5-12 (SPLENDOUR))	A randomised, open-label phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC.	Yes	11/12/2014	Regulatory in process	#551 (Gdansk)* ² #550 (Warsaw)* ³	0/313 (EORTC:500; All:1000)
1335* ¹ (SPECTALung)	SPECTALung: Screening Patients with Thoracic Tumors for Efficient Clinical Trial Access.	No	22/05/2015	Recruiting	#551 (Gdansk)* ⁴	13/ 117(/)
1416* ¹ (PEARLS)	A randomized, phase 3 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.	Yes	Regulatory in process	Recruiting	#550 (Warsaw) * ⁴ #5806 (Lodz)* ¹ #5820 (Otwock) * ⁴ #5804 (Poznan)* ¹	0/25 (All: 1380)
1417	A phase II study of etoposide and cis/carboplatin with or without MK3475 in untreated extensive small cell lung cancer.	No	Development		Sites selection	0/ 0 (152)
MELANOMA GROUP (EORTC MG)						
18081	Adjuvant peginterferon alpha-2b for 2 years vs Observation in patients with an ulcerated primary cutaneous melanoma with T(2-4)bNOM0: a randomized phase III trial of the EORTC Melanoma Group	Yes	23/10/2012	Recruiting	#550 (Warsaw)* ⁴	11/ 88 (All: 1200)
1208 (MiniTub)	Minitub: Prospective registry on Sentinel Node (SN) positive melanoma patients with minimal SN tumor burden who undergo Completion Lymph Node Dissections (CLND) or Nodal Observation	No	28/04/2015	Recruiting (Warsaw)	#550 (Warsaw)* ⁴ #552 (Krakow)* ²	2/32 (260)
1325* ¹	Adjuvant immunotherapy with anti-PD-1 monoclonal antibody Pembrolizumab (MK-3475) versus placebo after complete resection of high-risk Stage III melanoma: A randomized, double-blind Phase 3 trial of the EORTC Melanoma Group.	Yes	28/07/2015	Recruiting	#550 (Warsaw)* ⁴ #5800 (Poznan)* ⁴	5/553 (All: 900)
NETWORK OF CORE INSTITUTIONS (NOCI)						
90101 (CREATE)	Cross-tumoral Phase 2 clinical trial exploring crizotinib (PF-02341066) in patients with advanced tumors induced by causal alterations of ALK and/or MET ("CREATE")	No	27/08/2012	Recruiting	#550 (Warsaw)* ⁴	15 /132 (582)

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SOFT TISSUE AND BONE SARCOMA GROUP (EORTC STBSG)						
62092-22092 (STRASS)	A phase III randomized study of preoperative radiotherapy plus surgery versus surgery alone for patients with Retroperitoneal sarcomas (RPS) - STRASS	No	16/01/2012	Recruiting	#550 (Warsaw)* ⁴	10/213 (256)
1403 (rEECur)	International Randomised Controlled Trial of Chemotherapy for the treatment of recurrent and primary refractory Ewing sarcoma	No	10/03/2016	Regulatory in process	#550 (Warsaw)* ³	0/54 (390)
1447	Maintenance therapy with trabectedin vs observation after first line treatment with doxorubicin of patients with advanced or metastatic soft tissue sarcoma.	No	Development		#550 (Warsaw)* ² Sites selection	0/0 (All: 110)
1506 (ANITA)	Phase II multicenter study comparing the efficacy of the oral angiogenesis inhibitor nintedanib with the intravenous cytotoxic compound ifosfamide for treatment of patients with advanced metastatic soft tissue sarcoma after failure of systemic non-oxazaphosphorine-based first line chemotherapy for inoperable disease "ANITA"	No	Development		#550 (Warsaw)* ² Sites selection	0/0 (158)
RADIATION ONCOLOGY GROUP (EORTC ROG)						
22055 (LUNG-ART)	Phase III study comparing post-operative conformal radiotherapy to no post-operative radiotherapy in patients with completely resected non-small cell lung cancer and mediastinal N2 involvement - LUNG-ART	Yes	23/04/2013	Closed	#551 (Gdansk)* ⁴ #589 (Gliwice)* ³ #550 (Warsaw)* ³	0/381 (EORTC:114; All:700)
22113-08113 (LUNGTECH)	Stereotactic ablative radiotherapy (SABR) of inoperable centrally located NSCLC	No	27/11/2014	Regulatory in process	#551 (Gdansk)* ³ #589 (Gliwice)* ³	0/1 (150)

The information on institutions' financial support & study drugs' availabilities and insurance taken by the Sponsor will be provided by EORTC PM to the sites interested to participate; it is also available/can be obtained from Polish Liaison Officers

*1- Liaison Office is not involved in the set-up of the study

*2- Feasibility stage or site agreement negotiation/signature in process

*3- Site agreement signed; site under regulatory submissions and/or site docs collection

*4- Site is authorized to enter patients