Nr. crt.	Cod Protocol	Numar EudraCT	Medicament de investigatie clinica testat	Medicament de investigatie clinica comparator	Placebo	Aria terapeutică	Solicitant	Sponsor	International / national	Denumirea studiului	Faza	Nr. estimat de pacienti pt. Romania	Nr. de pacienti inrolati in Romania	Data autorizarii studiului clinic de catre ANMDM	Data aprobarii Comisiei de Etica	Data Inceperii Studiului	Inchidere studiu	Inchidere Temporara
1	**SB3-G31-BC, version 1.0, dated 08.11.2013**	2013-004172-35	SB3 (trastuzumab biosimilar)	Herceptin® (trastuzumab)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Samsung Bioepis Co., Ltd.	international	A Phase III Randomised, Double-Blind, Parallel Group, Multicentre Study to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity between SB3 (proposed trastuzumab biosimilar) and Herceptin® in Women with Newly Diagnosed HER2 Positive Early or Locally Advanced Breast Cancer in Neoadjuvant Setting	III	45		**05.06.2014**	**28.05.2014**	**25.06.2014**	**14.02.2017**	
2	**CRLX030A3301, version 00, dated 13.09.2013**	2013-002513-35	serelaxin (RLX030)	standard-of-care	Nu	Afecţiuni cardiovasculare	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services Romania SRL	international	A multicenter, prospective, randomized, open label study to assess the effect of serelaxin versus standard of care in acute heart failure (AHF) patients	III	56		**25.06.2014**		**04.08.2014**	**25.04.2017**	**22.03.2017**
3	**IC/VG/P01-2013, version ed.1/rev.0, dated 15.12.2013**	2013-005292-40	vaccin gripal trivalent purificat şi inactivat	Nu	Nu	Afecţiuni virale	Institutul Naţional de Cercetare-Dezvoltare pentru Microbiologie si Imunologie "Cantacuzino"	Institutul Naţional de Cercetare-Dezvoltare pentru Microbiologie si Imunologie "Cantacuzino"	naţional	The Study of the Immunogenity and Reactogenity of Trivalent, Purified, Inactivated Influenza Vaccine for Parenteral Administration in Adults, for the 2013-2014 Season, Produced by INCDMI Cantacuzino	IV	100		**16.01.2014**				
4	**AC-055-308, version 3, dated 19.09.2013**	2012-004411-31	macitentan (ACT-064992)	Nu	Nu	Afecţiuni cardiovasculare	Argint International Clinical Research & Development Services Kft. Teodora Dinu E-mail: teodora.dinu@argintinternational.com	Actelion Pharmaceuticals Ltd.	international	Long term, single-arm, open-label extension study of protocol AC-055-305 to assess the safety, tolerability and efficacy of macitentan in subjects with Eisenmenger Syndrome	III	8		**18.07.2014**	**26.05.2014**	**12.11.2014**		
5	**SP0969, dated 22.05.2013**	2012-004996-38	Vimpat® (lacosamide)	Nu	Da	Afecţiuni ale sistemului nervos	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail:comesioana@prainti.com	UCB BIOSCIENCES, Inc.	international	A Multicenter, Double blind, Randomized, Placebo controlled, Parallel group Study to Investigate the Efficacy and Safety of Lacosamide as Adjunctive Therapy in Subjects with epilepsy ≥4 Years to <17 Years of Age with Partial Onset Seizures	III	6		**18.07.2014**	**05.06.2014**	**05.12.2014**	**25.10.2016**	
6	**EP0934, dated 24.05.2013**	2012-005012-26	Vimpat® (lacosamide)	Nu	Nu	Afecţiuni ale sistemului nervos	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail: comesioana@prainti.com	UCB BIOSCIENCES, Inc.	international	A Multicenter, Open-label, Long-term extension Study to Investigate the Efficacy and Safety of Lacosamide as Adjunctive Therapy in Pediatric Subjects with epilepsy with Partial-Onset Seizures	III	6		**18.07.2014**	**11.11.2014**	**24.04.2015**		
7	**0624-301, version: Am#2 dated 11.12.2013**	2013-002453-29	Cinryze® (C1-INH)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Comac Medical SRL Diana Munteanu	Shire ViroPharma Incorporated	international	A phase 3, multicenter, randomized, single-blind, dose-ranging, crossover study to evaluate the safety and efficacy of intravenous administration of Cinryze® (C1 esterase inhibitor [human]) for the prevention of angioedema attacks in children 6 to 11 years of age with hereditary angioedema	III	1		**11.07.2014**	**22.05.2014**	**17.07.2014**	**28.12.2016**	
8	**ALK9072-003EXT2, version Final, dated 04.04.2013**	2013-001423-39	aripiprazole lauroxil (ALKS 9072)	Nu	Nu	Afecţiuni ale sistemului nervos	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Alkermes, Inc.	international	A Phase 3, Multicenter, Extension of Study ALK9072-003EXT to Assess the Long-term Safety and Durability of Effect of ALKS 9072 in Subjects with Stable Schizophrenia	III	25		**13.08.2014**		**17.10.2014**	**22.06.2016**	
9	**MK-8835-007 (Protocol B1521017 Pfizer) (Protocol 210226 Parexel), version 00, dated 20.09.2013**	2013-003290-95	ertugliflozin (MK-8835)	glimepiride	Da	Afecţiuni nutriţionale şi metabolice	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., USA	international	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, 26-Week Multicenter Study With a 78-Week Extension to Evaluate The Efficacy and Safety of Ertugliflozin in Subjects With Type 2 Diabetes Mellitus and Inadequate Glycemic Control on Metformin Monotherapy	III	62		**22.08.2014**	**05.06.2014**	**20.10.2014**		
10	**RO-2455-302-RD, version Final, dated 01.11.2013**	2013-001788-21	roflumilast	Nu	Da	Afecţiuni ale tractului respirator	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Takeda Development Centre Europe LTD	international	A multicenter, randomized, double-blind phase 3 study to evaluate tolerability and pharmacokinetics of 500µg roflumilast once daily with an up-titration regimen in COPD, including an open-label down-titration period evaluating tolerability and pharmacokinetics of 250µg roflumilast once daily in subjects not tolerating 500µg roflumilast once-daily	III	96		**30.05.2014**	**10.07.2014**	**19.08.2014**	**30.11.2015**	
11	**NX1207-IT-CL0414, version Final, dated 28.06.2013**	2012-002451-41	NX-1207	Omnexel® L.p. (tamsulosin hydrochloride)	Da	Afecţiuni ale sistemului urinar şi reproducător masculin	Recordati S.p.A. Federica Miotto	Recordati S.p.A.	international	Efficacy and Safety of a Single TRUS-guided Intraprostatic Injection of NX-1207 in Patients with Lower Urinary Tract Symptoms Associated with Benign Prostatic Hyperplasia: A Phase III European Clinical Study	III	30		**25.06.2014**	**10.07.2014**		**26.11.2014**	**12.11.2014**
12	**GWAP1241, version 1, dated 13.09.2013**	2013-000212-22	cannabidiol (GWP42003)	Nu	Da	Afecţiuni ale sistemului nervos	Octavian Florin Magazin Octavian Florin Magazin E-mail: octavian.magazin@gmail.com	GW Research Ltd	international	A double-blind, randomised, placebo-controlled, parallel group study of GWP42003 as adjunctive therapy in the first line treatment of schizophrenia or related psychotic disorder	II	40		**11.07.2014**	**06.05.2014**		**08.01.2015**	

13	**CT-P10-3.3, version 1.0, dated 04.11.2013**	2013-004493-96	CT-P10 (rituximab biosimilar)	Rituxan® (rituximab)	Nu	Afecţiuni oncologice	PPD Romania SRL Ana-Maria Tanase	CELLTRION, Inc.	internaţional	A Phase 1/3, Randomised, Parallel-Group, Active-Controlled, Double-Blind Study to Demonstrate Equivalence of Pharmacokinetics and Noninferiority of Efficacy for CT-P10 in Comparison With Rituxan, Each Administered in Combination With Cyclophosphamide, Vincristine, and Prednisone (CVP) in Patients With Advanced Follicular Lymphoma	III	12		**25.06.2014**		**19.01.2015**		
14	**TRx-237-007, version 5.0, dated 20.11.2013**	2011-005529-34	leuco-methylthioninium bis(hydromethanesulfonate) (LMTM/TRx0237)	Nu	Da	Afecţiuni ale sistemului nervos	Worldwide Clinical Trials Limited Marcelina Rybianska	TauRx Therapeutics Ltd	internaţional	A Double-Blind, Placebo-Controlled, Randomized, Parallel Group, 12-Month Safety and Efficacy Trial of Leuco-methylthioninium bis(hydromethanesulfonate) in Subjects with Behavioral Variant Frontotemporal Dementia (bvFTD)	III	6		**04.06.2014**		**27.10.2014**	**10.09.2015**	
15	**A3921133, version Final Amendment 3, dated 20.11.2013**	2013-003177-99	tofacitinib citrate (XeljanzB/CP-690,550-10)	Enbrel® (etanercept)	Nu	Afecţiuni ale sistemului imunitar	ICON Clinical Research srl Alin Balalau E-mail: alin.balalau@iconplc.com	Pfizer Inc., New York	internaţional	Phase 3b/4 randomized safety endpoint study of 2 doses of Tofacitinib in comparison to a tumor necrosis factor (TNF) inhibitor in subjects with rheumatoid arthritis	III/IV	92						
16	**CT-P10 3.2, version 2.0, dated 18.11.2013**	2013-004555-21	CT-P10 (rituximab biosimilar)	MabThera® (rituximab) Rituxan® (rituximab)	Nu	Afecţiuni ale sistemului imunitar	PPD Romania SRL Brindusa Stoica	CELLTRION, Inc.	internaţional	A Randomized, Controlled, Double-Blind, Parallel-Group, Phase 3 Study to Compare the Pharmacokinetics, Efficacy and Safety between CT-P10, Rituxan and MabThera in Patients with Rheumatoid Arthritis	III	8		**25.06.2014**		**11.11.2014**	**15.02.2017**	
17	**20130258, version 1.0, dated 30.10.2013**	2013-004654-13	ABP 501	Nu	Nu	Afecţiuni ale sistemului imunitar	Pharmaceutical Research Associates Romania SRL Roxana Dimitriu	Amgen Inc.	internaţional	An Open-Label, Single-arm Extension Study to Evaluate the Long-term Safety and Efficacy of ABP 501 in Subjects with Moderate to Severe Rheumatoid Arthritis	III	40		**27.06.2014**	**12.05.2014**	**04.03.2015**	**11.04.2016**	
18	**NAK-06, version 3.0, dated 05.12.2013**	2013-000894-56	Ibodutant (MEN15596)	Nu	Da	Afecţiuni ale sistemului digestiv	ICON Clinical Research srl Alin Balalau E-mail: alin.balalau@iconplc.com	Menarini Ricerche S.p.A.	internaţional	A 12-week double-blind, randomised, placebo-controlled, parallel group phase III study, followed by a 4-week randomised withdrawal period to evaluate the efficacy and safety of oral ibodutant 10 mg once daily in female patients with irritable bowel syndrome with diarrhoea (IBS-D)	III	52		**03.04.2014**	**16.05.2014**	**04.07.2014**	**22.06.2015**	
19	**MK-8835-001, version 00, dated 03.09.2013**	2013-003587-31	ertugliflozin (MK-8835)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Covance Clinical and Periapproval Services Limited Magdalena Paula Brebenel	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Efficacy and Safety of Ertugliflozin (MK-8835/PF-04971729) in Subjects with Type 2 Diabetes Mellitus with Stage 3 Chronic Kidney Disease Who Have Inadequate Glycemic Control on Background Antihyperglycemic Therapy	III	22		**18.07.2014**	**10.07.2014**	**09.09.2014**	**28.09.2016**	
20	**MK-8835-002, version 00, dated 25.09.2013**	2013-003582-34	ertugliflozin (MK-8835)	Glimepiride InvaGen (glimepiride)	Da	Afecţiuni nutriţionale şi metabolice	Covance Clinical and Periapproval Services Limited Magdalena Paula Brebenel	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Multicenter, Randomized, Double-Blind, Active-Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of the Addition of Ertugliflozin (MK-8835/PF-04971729) Compared With the Addition of Glimepiride in Subjects With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin	III	80		**11.07.2014**	**10.07.2014**	**29.08.2014**	**10.04.2017**	
21	**200820, version 00, dated 19.12.2013**	2013-004548-44	RELVAR ELLIPTA® (fluticasone Furoate + vilanterol)	vilanterol trifenatate	Nu	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Roxana Georgeta Gheorghiu E-mail: roxana.d.gheorghiu@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	A 12-Week Study to Evaluate the Efficacy and Safety of Fluticasone Furoate/Vilanterol Inhalation Powder (FF/VI) 100/25 mcg Once Daily Compared with Vilanterol Inhalation Powder (VI) 25 mcg Once Daily in Subjects with Chronic Obstructive Pulmonary Disease (COPD)	III	140		**16.07.2014**	**15.05.2014**	**19.01.2015**	**08.07.2015**	
22	**EMR 200559-005, version 2, dated 13.01.2014 VHP2013125**	2013-003126-83	cerdelimod (ONO-4641/MSC2430913A)	Avonex® (interferon beta-1A)	Da	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Merck KGaA	internaţional	A Phase III, Randomized, Double-Blind, Double Dummy, Multicenter Trial Comparing the Efficacy and Safety of 2 Doses of Daily Oral ONO 4641 (0.05 mg and 0.1 mg) versus Interferon-β-1a 30 µg IM Weekly in Subjects with Relapsing Multiple Sclerosis	III	35		**02.04.2014**			**08.09.2014**	
23	**EMR 200559-006, version 2, dated 13.01.2014 VHP2013124**	2013-002351-15	cerdelimod (ONO-4641/MSC2430913A)	Avonex® (interferon beta-1A)	Da	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Merck KGaA	internaţional	A Phase III, Randomized, Double-Blind, Double Dummy, Multicenter Trial Comparing the Efficacy and Safety of 2 Doses of Daily Oral ONO 4641 (0.05 mg and 0.1 mg) versus Interferon-β-1a 30 µg IM Weekly in Subjects with Relapsing-Remitting Multiple Sclerosis	III	35		**02.04.2014**			**08.09.2014**	
24	**54781532UCO2001, version INT -2, dated 21.01.2014**	2013-000263-88	JNJ-54781532-AAD	Nu	Da	Afecţiuni ale sistemului digestiv	SC Johnson& Johnson Romania SRL Monica Elena Dumitriu	Janssen-Cilag International NV	internaţional	A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Dose-response Study Evaluating the Efficacy and Safety of JNJ-54781532 in Subjects with Moderately to Severely Active Ulcerative Colitis	IIb	32		**03.09.2014**	**17.07.2014**	**15.09.2014**	**05.12.2015**	
25	**D0819C00003, (version 1, dated 08.11.2013 initial), version 2, dated 12.08.2014**	2013-005137-20	olaparib (AZD2281)	capecitabine vinorelbine eribulin	Nu	Afecţiuni oncologice	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A Phase III, Open Label, Randomised, Controlled, Multi-centre Study to assess the efficacy and safety of Olaparib Monotherapy versus Physician's Choice Chemotherapy in the Treatment of Metastatic Breast Cancer Patients with germline BRCA1/2 Mutations	III	9		**08.10.2014**	**31.07.2014**		**01.12.2016**	

26	**TH-CR-415, dated 15.01.2014**	2013-004698-29	TH-302	Alimta® (pemetrexed)	Da	Afecţiuni oncologice	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Threshold Pharmaceuticals, Inc.	internaţional	A Randomized Phase 2, Double-blind, Placebo-controlled, Multi-center Study Comparing Pemetrexed in Combination with TH-302 vs. Pemetrexed in Combination with Placebo as Second-line Chemotherapy for Advanced Non-Squamous, Non-Small Cell Lung Cancer	II	22		**30.05.2014**	**14.04.2014**	**17.07.2014**	**15.04.2016**	**23.12.2015**
27	**SP005, version 04, dated 05.12.2013**	2012-002814-38	DCVAC/PCa	Nu	Da	Afecţiuni oncologice	Chiltern International Limited Adana Bota E-mail: adana.bota@chiltern.com	SOTIO a.s.	internaţional	A Randomized, Double Blind, Multicenter, Parallel-group, Phase III study to evaluate efficacy and safety of DCVAC/PCa versus Placebo in Men with metastatic Castration Resistant Prostate Cancer eligible for 1st line chemotherapy	III	130		**12.05.2015**	**17.06.2014**			
28	**CT-P6-3.2, version 2.0, dated 20.01.2014**	2013-004525-84	CT-P6 (trastuzumab biosimilar)	Herceptin® (trastuzumab)	Nu	Afecţiuni oncologice	PPD Romania SRL Manuela Georgiana Botea	CELLTRION, Inc.	internaţional	A Phase 3, Double-Blind, Randomized, Parallel-Group, Active-Controlled Study to Compare the Efficacy and Safety of CT-P6 and Herceptin as Neoadjuvant and Adjuvant Treatment in Patients with HER2-Positive Early Breast Cancer	III	22		**16.10.2014**	**24.07.2014**	**27.11.2014**		
29	**NN7088-3908, version 1.0, dated 04.11.2013 VHP2013128**	2013-004025-88	turoctogog alfa pegol (N8-GP)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Novo Nordisk Farma SRL Catalin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S	internaţional	Safety and Efficacy of turoctocog alfa pegol (N8-GP) in Previously Untreated Patients with Haemophilia A An open-label single-arm multicentre non-controlled phase 3a trial investigating safety and efficacy of N8-GP in prophylaxis and treatment of bleeding episodes in previously untreated paediatric patients with severe haemophilia A	III	3		**17.04.2014**			**14.03.2016**	
30	**GWDM1302, version 2, dated 02.12.2013**	2013-001140-61	delta-9-tetrahydrocannabivarin (GWF42004)	Nu	Da	Afecţiuni nutriţionale şi metabolice	GW Research Ltd. Patrick Kerr	GW Research Ltd.	internaţional	A randomised, double blind, placebo controlled, parallel group, dose ranging study of GWF42004 as add on to metformin in the treatment of participants with Type 2 diabetes	II	70		**20.06.2014**			**29.12.2015**	
31	**NN9535-3625, version 2.0, dated 05.02.2014**	2013-004392-12	semaglutide	Lantus SoloStar® (insulin glargine)	Da	Afecţiuni nutriţionale şi metabolice	Novo Nordisk Farma SRL Catalin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S	internaţional	Efficacy and safety of semaglutide once weekly versus insulin glargine once daily as add on to metformin with or without sulphonylurea in insulin-naïve subjects with type 2 diabetes	III	30		**27.08.2014**	**02.06.2014**	**29.09.2014**	**03.09.2015**	
32	**CQGE031B2201E1, version 0, dated 06.11.2013 VHP2013129**	2013-003683-31	QGE031	Nu	Nu	Afecţiuni ale tractului respirator	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	An open-label, multi-center, extension study to evaluate the long-term safety of subcutaneous 240mg QGE031 given every 4 weeks for 52 weeks in allergic asthma patients who completed study CQGE031B2201	II	20		**02.04.2014**			**21.12.2015**	
33	**COSTAL-2013, version 1.0, dated 01.11.2013**	2013-004564-55	lamotrigine + sertraline (15/30 SER-LAM) (combinaţie)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Syncro Clinical Research SRL Gabor Brok E-mail: gbrok@syncrotrial.ro	MEDITOP Gyógyszeripari Kft	internaţional	A randomized, multicenter, double-blind, placebo controlled, parallel study to assess the efficacy and safety of the combined administration of sertraline and lamotrigine in subjects with chronic low back pain	II	50		**12.06.2014**	**23.06.2014**	**27.06.2014**	**13.01.2015**	
34	**WO29074, version 3, dated 25.02.2014 VHP2013127**	2013-003167-68	MPDL3280A (RO5541267) + Avastin® (bevacizumab)	Sutent® (sunitinib)	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd.	internaţional	A phase II, randomized study of atezolizumab (ANTI-PD-L1 Antibody) administered as monotherapy or in combination with Bevacizumab versus Sunitinib in patients with untreated advanced renal cell carcinoma	II	14		**27.03.2014**	**31.07.2014**	**14.01.2015**		
35	**CL2-20098-075, version Final, dated 06.12.2012**	2012-003404-12	agomelatine	Nu	Nu	Afecţiuni ale sistemului nervos	SERVIER PHARMA SRL Florin Ardelean E-mail: florin.ardelean@ro.netgrs.com	Institut de Recherches Internationales Servier	internaţional	Pharmacokinetics and safety of agomelatine in children (from 7 to less than 12 years) and adolescents (from 12 to less than 18 years) with Depressive or Anxiety Disorder. An open-labelled, multicenter, three-dose level, non-comparative study	II	10		**20.06.2014**	**26.06.2014**	**04.08.2014**	**14.03.2015**	
36	**DU176b-F-E308, vesion 1.0, dated 19.12.2013**	2013-003148-21	edoxaban tosylate (DU-176b)	Warfarin Teva® (warfarin) Clexane® (enoxaparin sodium)	Nu	Afecţiuni cardiovasculare	Covance Clinical and Perlapproval Services Limited Suzana Ivan E-mail: suzana.ivan@covance.com	Daiichi Sankyo Development Ltd.	internaţional	A prospective, randomised, open-label, blinded endpoint evaluation (PROBE) parallel group study comparing edoxaban (DU-176b) with enoxaparin/warfarin followed by warfarin alone in subjects undergoing planned electrical cardioversion of nonvalvular atrial fibrillation	III	51		**07.10.2014**	**24.07.2014**	**15.12.2014**	**04.02.2016**	
37	**A1481324, version Final, dated 25.09.2013**	2013-004362-34	sildenafil	Nu	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Pfizer Inc.	internaţional	A Multinational, Multicenter Study To Assess The Effects Of Oral Sildenafil On Mortality In Adults With Pulmonary Arterial Hypertension (PAH)	IV	30		**11.07.2014**	**25.09.2014**	**12.11.2014**		
38	**I7I-MC-XNAA, dated 17.12.2013**	2013-003552-21	LY2944876 (oxyntomodulin analogue)	Bydureon® (exenatide)	Da	Afecţiuni nutriţionale şi metabolice	Eli Lilly Romania SRL Andrada Maria Ioana Ionita E-mail: ionitaan@lilly.com	Eli Lilly and Company	internaţional	Comparison of the Oxyntomodulin Analog, LY2944876, to Once-Weekly Exenatide and to Placebo in Patients with Type 2 Diabetes	II	40		**29.07.2014**	**05.05.2014**	**13.08.2014**	**23.10.2015**	

39	**IB1001-04, version 1.3, dated 19.12.2013**	2013-003742-16	trenonacog alfa (IB1001/coagulation factor IX - recombinant)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Cangene Corporation	internaţional	Pharmacokinetics, Safety and Efficacy of Recombinant Factor IX Product, IB1001, in Patients with Severe Hemophilia B	III	3		**04.08.2014**			**12.05.2015**		
40	**CS001P3, version 3.0, dated 15.05.2013**	2010-019952-35	multikine (leukocyte interleukin)	standard-of-care Cyclophosphamide Injection® (cyclophosphamide) Indometacin Capsules BP 25mg® (indometacin) Multivitamins® (multivitamins with zinc)	Nu	Afecţiuni oncologice	Syncro Clinical Research SRL Gabor Brok E-mail: gbrok@syncrotrial.ro	CEL-SCI Corporation	internaţional	A Phase III, Open-label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery + Concurrent Chemoradiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only	III	20		**21.01.2015**	**01.07.2014**	**07.08.2015**		**26.09.2016**
41	**MK-8835-006, version 00, dated 16.12.2013**	2013-003697-26	ertugliflozin (MK-8835)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Covance Clinical and Periapproval Services Limited Alina Urjuma E-mail: Alina.Urjuma@covance.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Trial to Evaluate the Safety and Efficacy of Ertugliflozin (MK-8835/PF-04971729) in the Treatment of Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Metformin and Sitagliptin	III	38		**18.07.2014**		**01.10.2014**	**06.06.2016**	
42	**RIVAROXAFL3003, version INT-4.0, dated 11.10.2013**	2012-001491-11	rivaroxaban (BAY 59-7939)	standard-of-care (a vitamin K antagonist)	Nu	Afecţiuni cardiovasculare	S.C. BAYER S.R.L Corina Carpa-veche E-mail: corina.carpa-veche@bayer.com	Janssen-Cilag International NV	internaţional	An OPen-label, Randomized, Controlled, Multicenter Study Exploring TwO TreatmeNt StratEgiEs of Rivaroxaban and a Dose-Adjusted Oral Vitamin K Antagonist Treatment Strategy in Subjects With Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention - PIONEER AF-PCI	III	50		**22.10.2014**		**04.12.2014**	**29.07.2016**	
43	**CA209-026, (version 1.0, dated 20.12.2013 initial), version 2.0, dated 23.04.2014**	2012-004502-93	nivolumab (BMS-936558)	Paraplatin® (carboplatin) Cisplatin Neocorp® (cisplatin) Cisplatin Teva® (cisplatin) Gemcitabine® (gemcitabine hydrochloride) Alimta® (pemetrexed) Taxol® (paclitaxel)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	An Open-Label, Randomized, Phase 3 Trial of Nivolumab versus Investigator's Choice Chemotherapy as First-Line Therapy for Stage IV or Recurrent PD-L1+ Non-Small Cell Lung Cancer	III	50		**11.07.2014**	**12.06.2014**	**08.08.2014**		
44	**PPHM1202, version 4.1, dated 24.02.2014 VHP2013123**	2013-003953-13	bavituximab	Nu	Da	Afecţiuni oncologice	PPD Romania SRL Manuela Georgiana Botea E-mail: Manuela.Botea@ppdi.com	Peregrine Pharmaceuticals, Inc.	internaţional	A Phase III, Randomized, Double-Blind, Placebo-Controlled Multicenter Trial of Bavituximab Plus Docetaxel versus Docetaxel Alone in Patients with Previously Treated Stage IIIb/IV Non-Squamous Non-Small-Cell Lung Cancer	III	25		**02.04.2014**	**04.06.2014**	**01.08.2014**	**01.03.2017**	
45	**DSC/13/2984/05, version 1, dated 14.10.2013**	2013-003183-31	ITF2984	Octreotide® (octreotide)	Nu	Afecţiuni hormonale	Worldwide Clinical Trials Limited Mohammed Tirech mohammed.tirech@wwctrials.com Diana Tomescu E-mail: diana.tomescu@wwctrials.com	ITALFARMACO S.p.A.	internaţional	A Randomized, Multicenter, Phase II study to Investigate Efficacy and Safety of ITF2984 in Acromegalic patients	II	10		**23.07.2014**	**23.06.2014**		**08.02.2016**	
46	**CNTO136ARA3005, (version INT-1, dated 09.01.2014 initial), Amendment INT-2, dated 30.04.2014**	2013-001417-32	sirukumab (CNTO136)	Humira® (adalimumab)	Da	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Janssen-Cilag International N.V.	internaţional	A Multicenter, Randomized, Double-blind, Parallel Group Study of CNTO 136 (sirukumab) Administered Subcutaneously as Monotherapy Compared With Adalimumab Monotherapy, in Subjects with Active Rheumatoid Arthritis	III	16		**07.11.2014**		**16.12.2014**	**17.08.2016**	
47	**CD-IA-MEDI-546-1145, Amendment 2, dated 01.04.2013**	2012-004619-30	Medi-546	Nu	Nu	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	MedImmune, LLC, a wholly owned subsidiary of AstraZeneca, United States	internaţional	A Phase 2, Open-label Extension Study to Evaluate Long-term Safety of MEDI-546 in Adults with Systemic Lupus Erythematosus	II	2		**22.08.2014**	**16.06.2014**	**25.03.2015**		
48	**CFTY720D2311, version 02, dated 11.07.2013**	2011-005677-23	fingolimod (FTY720)	Avonex® (interferon beta-1A)	Da	Afecţiuni ale sistemului nervos	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Service AG	internaţional	A two-year, double-blind, randomized, multicenter, active controlled study to evaluate the safety and efficacy of fingolimod administered orally once daily versus interferon β-1a i.m. once weekly in pediatric patients with multiple sclerosis	III	2		**08.10.2014**	**24.06.2014**	**16.12.2014**		
49	**P-110881-01, version 1, dated 03.02.2014**	2014-000228-52	ozenoxacin	Nu	Da	Infecţii bacteriene şi micoze	Chiltern International Limited Adana Bota E-mail: adana.bota@chiltern.com	Ferrer Internacional, SA	internaţional	A phase III 2 arms, multicenter, randomised, double-blind study to assess the efficacy and safety of ozenoxacin 1% cream applied twice daily for 5 days versus placebo in the treatment of patients with impetigo	III	80		**18.09.2014**	**31.07.2014**		**02.02.2015**	
50	**MEA117113, version 01, dated 06.03.2014 VHP2014/05**	2013-004297-98	mepolizumab (SB-240563)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Andreea Manuela Cristescu E-mail: andreea.m.cristescu@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	Study MEA117113: Mepolizumab vs. Placebo as add-on treatment for frequently exacerbating COPD patients characterized by eosinophil level	III	65		**10.04.2014**	**16.06.2014**	**27.06.2014**	**16.01.2017**	
51	**GS-US-312-0123, Amendment 1, dated 19.02.2014 VHP2013143**	2013-003313-17	idelalisib (IDELA/GS-1101)	MabThera® (rituximab) Levact® (bendamustine hydrochloride)	Da	Afecţiuni oncologice	ICON Clinical Research SRL Alin Balaiau E-mail: alin.balaiau@iconplc.com	Gilead Sciences, Inc.	internaţional	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Bendamustine and Rituximab for Previously Untreated Chronic Lymphocytic Leukemia	III	12		**09.04.2014**		**09.09.2014**	**11.03.2016**	

52	**Z338-01, version 1.0, dated 11.10.2013**	2013-003342-16	Acofide® (acotiamide/Z-338)	Nu	Nu	Afecţiuni ale sistemului digestiv	Covance CAPS Ltd Andreea Curca E-mail: andreea.curca@covance.com	Zeria Pharmaceutical Co., Ltd.	internaţional	A Phase III, Multicentre, Single-arm, Open-label Study to Evaluate the Long-term Safety of Z-338 in Subjects with Functional Dyspepsia	III			**22.08.2014**		**06.10.2014**	**08.08.2016**		
53	**ESTEVE-SIGM-204, (version 5.0, dated 25.02.2014 initial), version 5.1, dated 07.07.2014**	2012-000400-14	E-52862	Nu	Da	Afecţiuni ale sistemului nervos	Premier Research Romania Andreea Cristina Dumitru E-mail: andreeacristina.dumitru@premier-research.com	Laboratorios del Dr. Esteve. S.A	internaţional	An exploratory, randomized, double blind, placebo controlled, parallel groups Phase II clinical trial to evaluate the efficacy and safety of E-52862 (400 mg) by oral route, in patients with painful diabetic neuropathy	II	120		**11.07.2014**	**10.07.2014**	**12.08.2014**	**04.12.2014**		
54	**200170, version 00, dated 07.05.2013**	2013-001371-20	eltrombopag (SB-497115)	Nu	Nu	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Andreea-Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Novartis Pharma Services AG	internaţional	Study 200170: A Rollover Study to Provide Continued Treatment with Eltrombopag	IV	1		**10.12.2014**					
55	**M14-115, version Administrative Changes 3 (incorporating Administrative Changes 1, 2 and 3), dated 18.03.2014 VHP2013134**	2013-001746-33	Humira® (adalimumab)	Nu	Da	Afecţiuni ale sistemului digestiv	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@iNCResearch.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A randomized, double-blind multicenter study of two adalimumab induction and maintenance dosing regimens in subjects with moderately to severely active Crohn's disease and evidence of mucosal ulceration	III	21		**23.04.2014**	**07.01.2015**	**30.03.2015**			
56	**TRIO-020, version 3.0, dated 12.11.2013**	2013-002192-18	afatinib (BIBW2992)	Nu	Nu	Afecţiuni oncologice	HT Research RO Cristina Dumbraveanu E-mail: cdumbraveanu@hungarotrial.com	Translational Research In Oncology, Canada	internaţional	A randomized open-label Phase II study of letrozole plus afatinib (BIBW2992) versus letrozole alone in first-line treatment of advanced ER+, HER2- postmenopausal breast cancer with low ER expression	II	40		**10.12.2014**		**13.07.2015**			
57	**MK-5172-062, version 00, dated 23.03.2014**	2014-000343-32	MK-5172 + MK-8742 (combinaţie)	Nu	Nu	Afecţiuni virale	Merck Sharp and Dohme Romania SRL Florina Prunduru E-mail: florina.prunduru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III Randomized Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 in Treatment-Naïve Subjects with Chronic HCV GT1, GT4, and GT6 Infection who are on Opiate Substitution Therapy	III	10		**29.05.2014**	**24.07.2014**	**11.09.2014**			
58	**201211, version 00, dated 06.03.2014**	2014-000529-19	umeclidinium bromide (GSK573719) + vilanterol (GW642444) (combinaţie)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Ana Magherusan E-mail: ana.l.magherusan@gsk.com	GlaxoSmithKline R&D	internaţional	A 12 week, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Evaluate the Efficacy of Umeclidinium/Vilanterol 62.5/25mcg in Subjects with COPD	III	55		**03.09.2014**	**28.07.2014**	**23.09.2014**	**05.03.2015**		
59	**ARD-3150-1201, version 2.0, dated 06.12.2013**	2013-005348-28	ciprofloxacin hydrochloride (Pulmaquin®/ARD-3150)	Nu	Da	Afecţiuni ale tractului respirator	ROTRIAL S.R.L. Greta Paun E-mail:greta_paun@rotrial.ro	Aradigm Corporation	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Pulmaquin® in the Management of Chronic Lung Infections with Pseudomonas aeruginosa in Subjects with Non-Cystic Fibrosis Bronchiectasis, including 28 Day Open-Label Extension and Pharmacokinetic Substudy (ORBIT-3)	III	12		**11.07.2014**	**30.07.2014**	**22.10.2014**	**12.08.2016**		
60	**ARD-3150-1202, version 1.0, dated 09.12.2013**	2013-005366-19	ciprofloxacin hydrochloride (Pulmaquin®/ARD-3150)	Nu	Da	Afecţiuni ale tractului respirator	ROTRIAL S.R.L. Greta Paun E-mail:greta_paun@rotrial.ro	Aradigm Corporation	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Pulmaquin® in the Management of Chronic Lung Infections with Pseudomonas aeruginosa in Subjects with Non-Cystic Fibrosis Bronchiectasis, including 28 Day Open-Label Extension (ORBIT-4)	III	20		**11.07.2014**	**30.07.2014**	**10.09.2014**	**20.07.2016**		
61	**LTS13463, dated 12.07.2013**	2013-002572-40	alirocumab (SAR236553/REGN727)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	sanofi-aventis Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	sanofi-aventis recherche et développement	internaţional	Open-Label Extension Study of EFC12492, R727-CL-1112, EFC12732 and LTS11717 Studies to Assess the Long-Term Safety and Efficacy of Alirocumab in Patients with Heterozygous Familial Hypercholesterolemia	III	5		**11.07.2014**	**05.08.2014**	**23.10.2014**			
62	**14861B, version 2.0, dated 19.02.2014**	2013-000001-23	Lu AE58054	Nu	Nu	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	H. Lundbeck A/S	internaţional	An open-label extension study to evaluate the long-term safety and tolerability of Lu AE58054 as adjunctive treatment to donepezil in patients with mild-moderate Alzheimer's disease	III	13		**26.09.2014**		**22.06.2015**			
63	**28431754DNE3001, (version Final, dated 10.12.2013 initial), Amendment INT-1, dated 12.06.2014**	2013-004494-28	Invokana® (canagliflozin/JNJ-28431754-ZAE)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Janssen-Cilag International N.V.	internaţional	A Randomized, Double-blind, Event-driven, Placebo-controlled, Multicenter Study of the Effects of Canagliflozin on Renal and Cardiovascular Outcomes in Subjects With Type 2 Diabetes Mellitus and Diabetic Nephropathy	III	146		**10.10.2014**		**09.12.2014**			
64	**MK-8835-005, version 00, dated 22.01.2014 (B1521019 Pfizer)**	2013-003698-82	ertugliflozin (MK-8835)	Januvia® (sitagliptin)	Da	Afecţiuni nutriţionale şi metabolice	Covance Clinical and Periapproval Services Limited Alina Urjuma E-mail: Alina.Urjuma@covance.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Randomized, Double-Blind, Multicenter Study to Evaluate the Efficacy and Safety of the Combination of Ertugliflozin (MK-8835/PF-04971729) with Sitagliptin Compared with Ertugliflozin Alone and Sitagliptin Alone, in the Treatment of subjects with T2DM With Inadequate Glycemic Control on Metformin Monotherapy	III	72		**29.07.2014**		**03.10.2014**	**01.06.2016**		

65	**ASA-CRP-01, (version 1.01, dated 21.01.2014 initial), version 1.02, dated 07.08.2014**	2014-000757-36	Acetylsalicylic acid® (acetylsalicylic acid)	Nu	Da	Afecţiuni ale sistemului nervos	ClinIRx Tangent Research SRL Paull George Radu E-mail: paull.radu@clinirxtangent.com	ClinIRx Tangent Research	naţional	A randomized trial administering aspirin vs. placebo as add-on to antipsychotics in patients with schizophrenia or schizoaffective disorder with high CRP levels	III	160		**07.10.2014**	**30.07.2014**	**03.11.2014**	**30.03.2016**	
66	**CRLX030A2209, (version 01, dated 11.01.2014 initial), version 02, dated 21.03.2014**	2013-002781-39	serelaxin (RLX030)	Nu	Da	Afecţiuni cardiovasculare	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	Prospective, Double-Blind, Multicenter Study Evaluating the Safety of Repeat Doses of IV Serelaxin in Subjects with Chronic Heart Failure	II	30		**29.07.2014**	**22.07.2014**	**16.09.2014**	**17.09.2015**	
67	**R668-AD-1224, (dated 11.12.2013 initial), Amendment 1, dated 07.07.2014**	2013-003254-24	dupilumab (SAR231893/REGN668)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Regeneron Pharmaceuticals, Inc.	internaţional	A randomized, double-blind, placebo-controlled study to demonstrate the efficacy and long-term safety of Dupilumab in adult patients with moderate-to-severe atopic dermatitis	III	45		**17.10.2014**	**10.12.2014**	**30.01.2015**	**19.10.2016**	
68	**GS-US-352-0101, Amendment 1.1, dated 12.02.2014 VHP2013140**	2013-002707-33	momelotinib (GS-0387)	Jakavi® (ruxolitinib)	Da	Afecţiuni oncologice	PRA Romania SRL Ioana Comes E-mail: comesioana@prainti.com	Gilead Sciences Inc.	internaţional	A Phase 3, Randomized, Double-blind Active-controlled Study Evaluating Momelotinib vs. Ruxolitinib in Subjects with Primary Myelofibrosis (PMF) or Post-Polycythemia Vera or Post-Essential Thrombocythemia Myelofibrosis (Post-PV/ET MF)	III	18		**23.04.2014**	**03.06.2014**	**18.07.2014**		
69	**CE01-301, version 1, dated 10.09.2013**	2013-003453-13	solithromycin (CEM-101)	Avelox® (moxifloxacin)	Da	Afecţiuni ale tractului respirator	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Cempra Pharmaceuticals, Inc.	internaţional	A Randomized, Double-Blind, Multi-Center Study to Evaluate the Efficacy and Safety of Intravenous to Oral Solithromycin (CEM-101) Compared to Intravenous to Oral Moxifloxacin in the Treatment of Adult Patients with Community-Acquired Bacterial Pneumonia	III	28		**25.07.2014**	**07.07.2014**	**28.10.2014**	**07.09.2015**	
70	**PM1116197, version 00, dated 14.02.2014**	2013-000657-50	losmapimod (GW856553)	Nu	Da	Afecţiuni cardiovasculare	GlaxoSmithKline (GSK) SRL Mirela Petronela Chiricescu E-mail: mirela.g.chiricescu@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	A Clinical Outcomes Study to Compare the Incidence of Major Adverse Cardiovascular Events in Subjects Presenting with Acute Coronary Syndrome Treated with Losmapimod Compared to Placebo (PM1116197) Short title: LosmApimod To Inhibit p38 MAP kinase as a TherapeUtic target and mzDIfy outcomes after an acute coronary syndromE (LATITUDE)-TIMI 60	III	345		**26.09.2014**	**28.07.2014**	**12.10.2014**	**08.12.2015**	
71	**M14-033, version Administrative Change 1, dated 21.03.2014 VHP201402**	2013-001682-16	Humira® (adalimumab)	Nu	Da	Afecţiuni ale sistemului digestiv	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Double-Blind, Randomized, Multicenter Study of Higher Versus Standard Adalimumab Dosing Regimens for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis	III	24		**30.04.2014**		**07.01.2015**		
72	**205.446, version 2.0, dated 25.02.2013**	2011-001777-43	tiotropium bromide	Nu	Da	Afecţiuni ale tractului respirator	Boehringer Ingelheim RCV GmbH & Co KG VIENA Sabina Marcu E-mail: sabina_elena.marcu@boehringer-ingelheim.com	Boehringer Ingelheim RCV GmbH & CoKG	internaţional	A randomised, double-blind, placebo-controlled, parallel-group trial to evaluate efficacy and safety of tiotropium inhalation solution (2.5 µg and 5 µg) delivered via Respimat® inhaler once daily in the evening over 12 weeks as add-on controller therapy on top of usual care in children (6 to 11 years old) with severe persistent asthma	III	8		**22.08.2014**	**06.08.2014**		**18.05.2015**	
73	**D589SC00001, version 1, dated 06.02.2014**	2013-004474-96	Symbicort Turbuhaler® (budesonide + formoterol fumarate)	Bricanyl Turbuhaler® (terbutaline sulfate) Pulmicort Turbuhaler® (budesonide)	Da	Afecţiuni ale tractului respirator	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A 52-week, double-blind, randomised, multi-centre, parallel-group, Phase III study in patients 12 years and older with asthma, evaluating the efficacy and safety of Symbicort® (budesonide/formoterol) Turbuhaler® 160/4.5 µg 'as needed' compared with terbutaline Turbuhaler® 0.4 mg 'as needed' and with Pulmicort® (budesonide) Turbuhaler® 200 µg twice daily plus terbutaline Turbuhaler® 0.4 mg 'as needed'	III	111		**12.11.2014**	**04.09.2014**			
74	**ISRCTN15088122, version 1.0, dated 01.10.2011, (including Appendix 4 version 2.0, dated 21.08.2014 Country specific)**	2011-003669-14	Cyklokapron® (tranexamic acid)	Nu	Da	Afecţiuni limfatice şi ale sângelui	London School of Hygiene and Tropical Medicine Ian Roberts E-mail:crash.mail@lshtm.ac.uk	London School Of Hygiene and Tropical Medicine, UK	internaţional	Tranexamic Acid for the treatment of significant traumatic brain injury: an international, randomised, double blind, placebo controlled trial	III	500		**03.10.2014**				
75	**200699, version 00, dated 25.02.2014**	2014-000883-16	fluticasone furoate + umeclidinium bromide (combinaţie)	fluticasone furoate vilanterol Relvar Ellipta® (fluticasone furoate + vilanterol trifenatate)	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Ana Magherusan E-mail: ana.l.magherusan@gsk.com	GlaxoSmithKline Research & Devlopment Ltd	internaţional	A Clinical Study to Evaluate Four Doses of Umeclidinium Bromide in Combination with Fluticasone Furoate in COPD Subjects with an Asthmatic Component	II	60		**18.09.2014**	**28.07.2014**	**05.10.2014**	**18.07.2015**	
76	**CQVA149A3401, version 03, dated 28.03.2014 VHP2013136**	2013-003127-11	Seebri Breezhaler® (glycopyrronium bromide)/Ultibro Breezhaler® (glycopyrronium bromide + indacaterol maleate)	salbutamol ipratropium bromide salbutamol + ipratropium bromide formoterol salmeterol indacaterol tiotropium bromide aclidinium bromide beclometasone fluticasone salmeterol + fluticasone formoterol + budesonide	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A prospective, multicenter, 12-week, randomized open-label study to evaluate the efficacy and safety of glycopyrronium (50 micrograms o.d.) or indacaterol maleate and glycopyrronium bromide fixed-dose combination (110/50 micrograms o.d.) regarding symptoms and health status in patients with moderate chronic obstructive pulmonary disease (COPD) switching from treatment with any standard COPD regimen	IV	2500		**29.05.2014**		**14.01.2015**	**29.04.2016**	
77	**F17464 GE 2 01, (version 3, dated 18.04.2014 initial), version 4, dated 02.07.2014**	2013-005451-32	F17464	Nu	Da	Afecţiuni ale sistemului nervos	SC Comac Medical SRL Boyan Ivanov Slavov E-mail:boyan.slavov@comac-medical.com	Pierre Fabre Médicament represented by the Institut de Recherche Pierre Fabre (IRPF)	internaţional	Effects of F17464 in acute exacerbation of schizophrenia	II	80		**08.10.2014**		**05.11.2014**	**22.12.2015**	

78	**AB12006, version 3.0, dated 21.11.2013**	2013-000490-79	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni oncologice	HT Research RO Daniela Marchidanu E-mail: dmarchidanu@hungarotrial.com	AB Science	internaţional	A prospective, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with FOLFIRI (irinotecan, 5-fluorouracil and folinic acid) to placebo in combination with FOLFIRI in second line treatment of patients with metastatic colorectal cancer	III	200						
79	**RB-FVIIa-006-13, Amendment 3, dated 27.03.2014 VHP201412**	2013-004779-11	Coagulation Factor VIIa (Recombinant) (LR769)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	rEVO Biologics, Inc.	internaţional	A Phase III Study on the Safety, Pharmacokinetics and Efficacy of Coagulation Factor VIIa (Recombinant) in Congenital Hemophilia A or B Patients with Inhibitors to Factor VIII or IX	III	3		**28.05.2014**	**04.06.2014**		**31.07.2015**	
80	**DB2116961, version 04, dated 09.04.2014**	2013-001827-38	umeclidinium bromide (GSK573719) + vilanterol (GW642444) (combinaţie)	Spiriva® (tiotropium bromide) Ombrez Breezhaler® (indacaterol maleate)	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Ana Magherusan E-mail: ana.l.magherusan@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	Study DB2116961, a multicentre, randomised, blinded, parallel group study to compare UMEC/VI (UmeclidiniumVilanterol) in a fixed dose combination with Indacaterol plus Tiotropium in symptomatic subjects with moderate to very severe COPD	III	90		**07.10.2014**	**11.09.2014**	**21.10.2014**	**04.05.2015**	
81	**A0081105, Final Protocol, dated 26.07.2012**	2010-023263-18	Lyrica® (pregabalin)	Nu	Da	Afecţiuni ale sistemului nervos	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Pfizer Inc.	internaţional	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Trial Of Pregabalin As Adjunctive Therapy In Pediatric And Adult Subjects With Primary Generalized Tonic-Clonic Seizures	III	24		**17.10.2014**		**26.11.2014**		
82	**201316, (version 00, dated 03.04.2014 initial), version 01, dated 22.05.2014**	2014-000884-42	umeclidinium bromide (GSK573719)	Spiriva® (tiotropium bromide)	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Andreea Manuela Cristescu E-mail: andreea.m.cristescu@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	A Randomized, Blinded, Double-dummy, Parallel-group Study to Evaluate the Efficacy and Safety of Umeclidinium (UMEC) 62.5 mcg compared with Tiotropium 18 mcg in Subjects with Chronic Obstructive Pulmonary Disease (COPD)	III	86		**24.09.2014**		**03.10.2014**	**15.06.2015**	
83	**201315, version 00, dated 03.04.2014**	2014-000885-23	umeclidinium bromide (GSK573719)	Seebri Breezhaler® (glycopyrronium bromide)	Nu	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Roxana Georgeta Gheorghiu E-mail: roxana.d.gheorghiu@gsk.com	GlaxoSmithKline Research and Development	internaţional	A Randomized, Parallel-group, Open-label Study to Evaluate the Efficacy and Safety of Umeclidinium (UMEC) 62.5 mcg compared with Glycopyrronium 44 mcg in Subjects with Chronic Obstructive Pulmonary Disease (COPD)	III	85		**10.09.2014**		**30.09.2014**	**03.06.2015**	
84	**D3251C00003, (version 2.0, dated 23.04.2014 initial), version 1.0, dated 24.01.2014 + Amendment 1, dated 17.04.2014**	2013-004590-27	benralizumab (Medi-563)	Nu	Da	Afecţiuni ale tractului respirator	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca	internaţional	A Randomised, Double-blind, Chronic Dosing (56 week) Placebo-controlled, Parallel Group, Multicentre, Phase III Study to Evaluate the Efficacy and Safety of 2 Doses of Benralizumab (MEDI-563) in Patients with Moderate to Very Severe Chronic Obstructive Pulmonary Disease (COPD) with a History of COPD Exacerbations (GALATHEA)	III	88		**20.10.2014**				
85	**CT-P13-3.4, version 1.2, dated 20.03.2014**	2013-004497-10	Remsima® (infliximab/CT-P13)	Remicade® (infliximab)	Nu	Afecţiuni ale sistemului digestiv	PPD Romania SRL Geanina Maria Atitiene	Celltrion, Inc.	internaţional	A Randomized, Double-Blind, Parallel-Group, Phase 3 Study to Demonstrate Noninferiority in Efficacy and to Assess the Safety of CT-P13 Compared to Remicade in Patients With Active Crohn's Disease	III	25		**31.10.2014**	**24.10.2014**	**08.01.2015**	**15.02.2017**	
86	**TV1106-IMM-20001, dated 09.04.2014**	2013-004468-69	albutropin (TV1106)	Genotropin® (somatropin)	Nu	Afecţiuni hormonale	Accelsiors S.R.L Monica Roxana Velculescu E-mail: m.velculescu@accelsiors.com	Teva Pharmaceutical Industries, Ltd.	internaţional	A Phase 2, Randomized, Open-Label, Safety and Dose-Finding Study Comparing 3 Different Doses of Weekly TV-1106 and Daily Recombinant Human Growth Hormone (Genotropin®) Therapy in Treatment-Naïve, Pre-Pubertal, Growth Hormone-Deficient Children	II	15		**17.10.2014**		**08.12.2014**	**18.12.2015**	
87	**20130109, version 1.0, dated 26.02.2014**	2013-005542-11	rituximab (ABP 798)	Rituxan® (rituximab)	Nu	Afecţiuni limfatice şi ale sângelui	PRA Romania SRL Ioana Comes E-mail:comesioana@praintl.com	Amgen Inc.	internaţional	A Randomized, Double-Blind Study Evaluating the Efficacy, Safety and Immunogenicity of ABP 798 Compared with Rituximab in Subjects with CD20 Positive B-Cell Non-Hodgkin Lymphoma (NHL)	III	3		**05.11.2014**	**15.01.2015**	**17.02.2017**		
88	**261202, version Original, dated 07.03.2014**	2014-000742-30	PEGylated rFVIII (BAX855)	Advate 1000 IU® (octogog alfa)	Nu	Afecţiuni limfatice şi ale sângelui	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Baxter Innovations GmbH	internaţional	A phase 3 prospective, uncontrolled, multicenter study evaluating pharmacokinetics, efficacy, safety, and immunogenicity of BAX 855 (PEGylated full-length Recombinant FVIII) in previously treated pediatric patients with severe hemophilia A	III	4		**26.11.2014**	**05.11.2014**			
89	**COBW251X2101, version 07, dated 25.04.2014**	2011-005085-37	QBW251	Nu	Da	Afecţiuni ale tractului respirator	Novartis Pharma Services Romania SRL Alexandru Ionel E-mail: alexandru.ionel@novartis.com	Novartis Pharma Services AG	internaţional	A randomized, double blind placebo-controlled study to assess the safety, tolerability, pharmacokinetics, and preliminary pharmacodynamics of single and multiple ascending doses of QBW251 in healthy subjects and multiple doses in cystic fibrosis patients	II	6		**22.08.2014**		**06.10.2014**	**20.11.2015**	**29.09.2015**
90	**I3Y-MC-JPBL, dated 01.04.2014**	2013-004728-13	LY2835219 Faslodex® (fulvestrant)	Nu	Da	Afecţiuni oncologice	Eli Lilly Romania SRL Carmen Alina Toader E-mail: toader_carmen_alina@network.lilly.com	Eli Lilly and Company	internaţional	MONARCH 2: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of Fulvestrant with or without Abemaciclib, a CDK4/6 Inhibitor, for Women with Hormone Receptor Positive, HER2 Negative Locally Advanced or Metastatic Breast Cancer	III	10		**26.11.2014**	**13.10.2014**	**08.01.2015**		

91	**8228-001, (version 1, dated 28.01.2014 initial), version 03, dated 10.12.2014**	2013-003831-31	letermovir (MK-8228)	Nu	Da	Afecţiuni virale	Merck Sharp and Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III Randomized, Placebo-controlled Clinical Trial to Evaluate the Safety and Efficacy of MK-8228 (Letermovir) for the Prevention of Clinically Significant Human Cytomegalovirus (CMV) Infection in Adult, CMV-Seropositive Allogeneic Hematopoietic Stem Cell Transplant Recipients	III	20		**12.03.2015**	**20.10.2014**	**05.05.2015**	**24.08.2016**	**02.03.2016**
92	**WA29249, version 1, dated 28.02.2014 VHP201427**	2013-004625-81	lebrikizumab (RO5490255)	Singulair® (montelukast)	Da	Afecţiuni ale sistemului respirator	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A phase III, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of Lebrikizumab in adult patients with mild to moderate asthma	III	16		**10.06.2014**		**18.11.2014**	**22.01.2016**	
93	**B3281006, Amendment 1, dated 08.05.2014 VHP201421**	2014-000132-41	Rituximab-Pfizer (PF-05280586)	MabThera® (rituximab)	Nu	Afecţiuni oncologice	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Pfizer Inc., New York	internaţional	A Phase 3, Randomized, Double-Blind Study of PF-05280586 Versus Rituximab for the First-Line Treatment of Patients with CD20-Positive, Low Tumor Burden, Follicular Lymphoma	III	35		**24.06.2014**		**11.12.2014**		
94	**B5371002, version Final, dated 27.02.2014 VHP201422**	2013-004148-49	Infliximab-Pfizer (PF-06438179)	Remicade® (infliximab)	Nu	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Pfizer Inc.	internaţional	A Phase 3 Randomized, Double-blind study assessing the efficacy and safety of PF- 06438179 and infliximab in combination with methotrexate in subjects with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate	III	27		**18.06.2014**		**17.02.2015**	**01.06.2017**	
95	**CLDT600A2306, (version 00, dated 09.12.2013 initial), version 01, dated 05.03.2015**	2012-004942-14	Sebivo® (telbivudine)	Nu	Da	Afecţiuni virale	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A randomized, double-blind, 104-weeks treatment study to evaluate the efficacy, safety, tolerability and pharmacokinetics of telbivudine oral solution and tablets in children and adolescents with compensated HBeAg-positive and negative chronic hepatitis B virus infection P/119/2010, P/203/2011, P/236/2012	III	30		**15.06.2015**		**23.10.2015**	**06.01.2017**	**24.11.2016**
96	**AB12003, version 2.0, dated 17.10.2013**	2013-000809-23	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni oncologice	HT Research RO Natalia Neagoe E-mail: naneagoe@hungarotrial.com	AB Science	internaţional	A prospective, multicenter, randomized, double blind, placebo-controlled, 2-parallel groups, phase 3 study to compare the efficacy and safety of masitinib in combination with docetaxel to placebo in combination with docetaxel in first line metastatic Castrate Resistant Prostate Cancer (mCRPC)	III	40						
97	**AB12005, version 3.0, dated 19.11.2013**	2013-002293-41	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni oncologice	HT Research RO SRL Nicoleta Carp E-mail: ncarp@hungarotrial.com	AB Science	internaţional	A prospective, multicenter, double-randomised, double-blind, 2-parallel groups, phase 3 study to compare as first line therapy efficacy and safety of masitinib in combination with gemcitabine, to gemcitabine in combination with placebo, followed as second line treatment by masitinib in combination with Folfiri.3 versus placebo in combination with Folfiri.3 in the treatment of patients with non resectable locally advanced or metastatic pancreatic cancer	III	80						
98	**1200.217, version 1, dated 10.04.2014**	2014-001077-14	Giotrif® (afatinib/BIBW 2992)	Nu	Nu	Afecţiuni oncologice	Dokumeds CRO SRL Luminiţa Neferu E-mail: luminita.neferu@dokumeds.com	Boehringer Ingelheim RCV GmbH & CoKG	internaţional	An open label, single-arm phase IV study to assess the efficacy and safety of afatinib as second-line therapy for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harbouring an EGFR mutation (Del19 or L858R) who have failed first-line treatment with platinum-based chemotherapy	IV	100		**17.12.2014**	**16.10.2014**	**13.01.2015**	**13.06.2017**	
99	**200304, version 01, dated 30.04.2014**	2014-001057-17	dolutegravir (GSK1349572)	Kaletra® (lopinavir + ritonavir)	Nu	Afecţiuni virale	GlaxoSmithKline (GSK) SRL Mirela Chiricescu E-mail: mirela.g.chiricescu@gsk.com	ViiV Healthcare	internaţional	A Phase 3b, randomised, open-label study of the antiviral activity and safety of dolutegravir compared to lopinavir/ritonavir both administered with dual nucleoside reverse transcriptase inhibitor therapy in HIV-1 infected adult subjects with treatment failure on first line therapy	III	25		**05.02.2015**	**28.07.2014**	**25.02.2015**	**04.04.2017**	
100	**CSL627_3001, Amendment v1.0, dated 28.03.2014**	2013-003262-13	lonoctocog alfa (CSL627/rVIII-SingleChain)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	CSL Behring GmbH	internaţional	A Phase III Open Label, Multicenter, Extension Study to Assess the Safety and Efficacy of Recombinant Coagulation Factor VIII (rVIII-SingleChain, CSL627) in Subjects with Severe Hemophilia A	III	15		**30.10.2014**		**03.12.2014**		
101	**MYL-GAI-3002, version 2.0, dated 16.04.2014**	2014-000881-23	Basalog® (insulin glargine)	Lantus SoloStar® (insulin glargine)	Nu	Afecţiuni nutriţionale şi metabolice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	MYLAN GmbH	internaţional	An open-label, randomized, multi-center, parallel-group clinical trial comparing the efficacy and safety of Mylan's Insulin glargine with Lantus® in type 2 Diabetes Mellitus patients	III	43		**13.03.2015**				
102	**MW2010-03-02, version 5, dated 08.05.2014**	2014-001672-55	NexoBrid® (concentrate of proteolytic enzymes enriched in bromelain)	Collagenase Santyl Ointment®	Da	Leziuni, intoxicaţii şi afecţiuni profesionale	Rotrial Contract Research S.R.L. Greta Paun E-mail: greta_paun@rotrial.ro	MediWound Ltd.	internaţional	A multicenter, multinational, randomized, controlled, assessor blinded study, performed in subjects with thermal burns, to evaluate the efficacy and safety of NexoBrid compared to Gel Vehicle and compared to Standard of Care	III	30		**30.10.2014**	**24.09.2014**	**22.09.2015**		
103	**DPM-CF-303, version 1.8, dated 27.03.2014**	2013-005357-79	Bronchitol® (mannitol)	Nu	Da	Afecţiuni ale tractului respirator	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	Pharmaxis Limited	internaţional	Long Term Administration of Inhaled Mannitol in Cystic Fibrosis – A Safety and Efficacy Trial in Adult Cystic Fibrosis Subjects	III	21		**20.04.2015**	**22.12.2014**		**21.02.2017**	

104	**MO25757, version 2.0, dated 25.02.2013**	2011-002009-31	Avastin® (bevacizumab)	Nu	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A single arm open label multicentre extension study of bevacizumab in patients with solid tumours on study treatment with bevacizumab at the end of a F. Hoffmann-La Roche and/or Genentech sponsored study	IV	5		**12.11.2014**				
105	**SPL7013-018, version Final 2.0, dated 12.05.2014**	2014-000694-39	astodrimer sodium (SPL7013/VivaGel®)	Nu	Da	Infecţii bacteriene şi micoze	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Starpharma Pty Ltd	internaţional	A phase 3, double-blind, multicentre, randomised, placebo-controlled study to determine the efficacy and safety of SPL7013 Gel (VivaGel®) to prevent the recurrence of bacterial vaginosis	III	161		**17.04.2015**	**16.12.2014**	**27.05.2015**	**09.09.2016**	
106	**CBYM338D2201, version 01, dated 10.02.2014**	2013-003439-31	bimagrumab (BYM338)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A 24-week double blind treatment and 24-week follow up, randomized, multi-center, placebo-controlled, phase IIa/IIb study to evaluate the safety and efficacy of i.v. bimagrumab on total lean body mass and physical performance in patients after surgical treatment of hip fracture	II	10		**27.04.2015**			**31.05.2017**	**16.06.2015** **25.02.2016**
107	**BAYQ3939/15626, (version 1.0, dated 04.11.2013 initial), version 2.0, dated 02.10.2014**	2013-004659-19	ciprofloxacin (BAYQ3939)	Nu	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail:andreea-raluca.ghinea@parexel.com	Bayer AG (BAG)	internaţional	Randomized, double-blind, placebo-controlled, multicenter study comparing Ciprofloxacin DPI 32.5 mg BID intermittently administered for 28 days on / 28 days off or 14 days on / 14 days off versus placebo to evaluate the time to first pulmonary exacerbation and frequency of exacerbations in subjects with non–cystic fibrosis bronchiectasis	III	21		**27.02.2015**		**20.03.2015**	**19.10.2016**	
108	**M12-914, Amendment 1, dated 12.06.2014** **VHP462 (VHP201433)**	2014-000345-70	veliparib (ABT-888)	Paclitaxel® (paclitaxel) Carboplatin® (carboplatin)	Da	Afecţiuni oncologice	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase III Randomized, Placebo-Controlled Trial of Carboplatin and Paclitaxel with or without the PARP Inhibitor Veliparib (ABT-888) in Her-2 Negative Metastatic or Locally Advanced Unresectable BRCA-Associated Breast Cancer	III	50		**23.07.2014**	**07.01.2015**	**01.04.2015**		
109	**CTT116855, version 02, dated 10.04.2014** **VHP201442**	2013-003075-35	fluticasone furoate (GW685698) + umeclidinium (GSK573719) + vilanterol trifenatate (GW642444) (combinaţie, GSK2834425)	Relvar Ellipta® (fluticasone furoate + vilanterol trifenatate) umeclidinium + vilanterol trifenatate (combinaţie)	Nu	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Andreea Manuela Cristescu E-mail: andreea.m.cristescu@gsk.com	GlaxoSmithKline Research & Development Ltd.	internaţional	A phase III, 52 week, randomized, double-blind, 3-arm parallel group study, comparing the efficacy, safety and tolerability of the fixed dose triple combination FF/UMEC/VI with the fixed dose dual combinations of FF/VI and UMEC/VI, all administered once-daily in the morning via a dry powder inhaler in subjects with chronic obstructive pulmonary disease	III	100		**23.07.2014**	**31.07.2014**	**11.08.2014**	**14.06.2016**	
110	**DUR001-303, Amendment 1, dated 26.03.2014** **VHP201445**	2014-000419-15	dalbavancin (DUR001)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	Pharm-Olam International (UK) Ltd. Catalina Teodor E-mail: catalina.teodor@pharm-olam.com	Durata Therapeutics International B.V.	internaţional	A Phase 3b, Double-Blind, Multicenter, Randomized Study to Compare the Efficacy and Safety of Single Dose Dalbavancin to a Two Dose Regimen of Dalbavancin for the Treatment of Acute Bacterial Skin and Skin Structure Infections	III	40		**31.07.2014**			**23.12.2014**	
111	**I3Y-MC-JPBK, dated 13.05.2014**	2013-004662-33	LY2835219	Tarceva® (erlotinib)	Nu	Afecţiuni oncologice	Eli Lilly Romania SRL Carmen Alina Toader E-mail: toader_carmen_alina@network.lilly.com	Eli Lilly and Company	internaţional	JUNIPER: A Randomized Phase 3 Study of Abemaciclib plus Best Supportive Care versus Erlotinib plus Best Supportive Care in Patients with Stage IV NSCLC with a Detectable KRAS Mutation Who Have Progressed After Platinum-Based Chemotherapy	III	16		**27.02.2015**	**24.09.2014**	**17.07.2015**		
112	**GA29103, version 3, dated 09.07.2014** **VHP201435**	2013-004282-14	etrolizumab (Ro 549-0261/F04)	Remicade® (infliximab)	Da	Afecţiuni ale sistemului digestiv	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	Phase III, randomized, multicenter, double-blind, double dummy study to evaluate the efficacy and safety of etrolizumab compared with infliximab in patients with moderate to severe active ulcerative colitis who are naive to TNF inhibitors	III	46		**04.08.2014**		**05.05.2015**		
113	**GA28951, version 4, dated 04.07.2014** **VHP201434**	2013-004435-72	etrolizumab (Ro 549-0261/F04)	Nu	Nu	Afecţiuni ale sistemului digestiv	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	An Open Label Extension and Safety Monitoring Study of Moderate to Severe Ulcerative Colitis Patients Previously Enrolled in Etrolizumab Phase III Studies	III	46		**04.08.2014**		**22.11.2016**		
114	**17712 (3104007), version 1, dated 10.03.2014**	2013-003820-36	BAY 1841788	Nu	Da	Afecţiuni oncologice	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Bayer AG (BAG)	internaţional	A Multinational, Randomised, Double-Blind, Placebo-Controlled, Phase III Efficacy and Safety Study of BAY 1841788 in Men with High-risk Non-Metastatic Castration-Resistant Prostate Cancer	III	20		**22.12.2014**	**03.11.2014**	**28.01.2015**		
115	**D4191C00004, version 01, dated 05.03.2014** **VHP201448**	2014-000338-46	MEDI4736	Gemcitabine® (gemcitabine) Navelbine® (vinorelbine) Tarceva® (erlotinib)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	AstraZeneca AB	internaţional	A Phase III, Open-label, Randomised, Multi-centre, International Study of MEDI4736, Given as Monotherapy or in Combination with Tremelimumab, Determined by PD-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)	III	24		**26.08.2014**	**14.05.2015**	**15.06.2015**		
116	**GS-US-312-0133, Amendment 1, dated 06.05.2014** **VHP201454**	2013-003314-41	idelalisib (IDELA, GS-1101) MabThera® (rituximab)	Nu	Nu	Afecţiuni oncologice	ICON Clinical Research SRL Alin Bălălău E-mail:alin.balalau@iconplc.com	Gilead Sciences, Inc.	internaţional	A Phase 2, Single Arm Study Evaluating the Efficacy and Safety of Idelalisib in Combination with Rituximab in Patients with Previously Untreated Chronic Lymphocytic Leukemia with 17p Deletion	II	4		**13.08.2014**		**17.12.2014**	**07.03.2016**	

117	**M12-963, Amendment 1, dated 14.04.2014 VHP201453**	2013-004019-37	ABT-122	Adalimumab® (adalimumab)	Da	*Afecţiuni ale sistemului imunitar*	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	*internaţional*	A Phase 2 Study to Investigate the Safety and Efficacy of ABT-122 Given with Methotrexate in Subjects with Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate	II	20		**13.08.2014**	**22.10.2014**	**22.10.2015**	**30.11.2015**	
118	**MK-3475-042, version 00, dated 18.06.2014**	2014-001473-14	pembrolizumab (MK-3475/SCH900475)	Alimta® (pemetrexed) Paclitaxel® (paclitaxel) Carboplatin® (carboplatin)	Nu	*Afecţiuni oncologice*	Merck Sharp and Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	*internaţional*	A Randomized, Open Label, Phase III Study of Overall Survival Comparing Pembrolizumab (MK-3475) versus Platinum Based Chemotherapy in Treatment Naive Subjects with PD-L1 Positive Advanced or Metastatic Non-Small Cell Lung Cancer (Keynote 042)	III	70		**06.03.2015**	**09.02.2015**	**12.05.2015**		**20.11.2015 02.03.2016**
119	**CV185-267 (B0661025), (version Final, dated 19.03.2014), Amendment 2, dated 16.02.2015**	2014-001231-36	Eliquis® (apixaban/ BMS-562247-01)	vitamin K antagonist enoxaparin	Nu	*Afecţiuni cardiovasculare*	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	*internaţional*	A phase IV trial to assess the effectiveness of Apixaban compared with usual care anticoagulation in subjects with non-valvular Atrial Fibrillation undergoing cardioversion	IV	60		**10.06.2015**	**15.12.2014**	**24.07.2015**	**09.11.2016**	
120	**OPV116910, version 5, dated 13.03.2014**	2013-001370-20	ofatumumab (GSK1841157)	Nu	Da	*Afecţiuni ale pielii şi ţesutului conjunctiv*	PPD Romania SRL Brindusa Ilse Stoica E-mail:brindusa.stoica@ppdi.com	Novartis Pharma AG, Switzerland	*internaţional*	OPV116910: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Investigate the Efficacy and Safety of Ofatumumab Injection for Subcutaneous Use in Subjects with Pemphigus Vulgaris	III	35		**30.06.2015**		**23.11.2015**		
121	**EMR 200136_583, Version 2.0, dated 29.06.2014**	2014-001290-14	Rebif®	Nu	Nu	*Afecţiuni ale sistemului nervos*	CEBIS International SRL Mihai Ioan Manolache E-mail:office@cebis-int.com	Merck Romania SRL	*internaţional*	Prospective Phase IV Clinical Trial on Effectiveness and adherence to Rebif Treatment of CIS and RMS Patients in Romania by using Electronic Device RebiSmart™	IV	100		**24.10.2014**	**16.10.2014**	**19.12.2015**	**06.08.2016**	
122	**BTA798-203, (version 2.0, dated 21.07.2014 initial), version 3.0, dated 21.11.2014**	2014-001785-95	vapendavir	Nu	Da	*Afecţiuni virale*	August Research SRL Andreea Catalina Stoenescu E-mail: cstoenescu@augustresearch.com	Biota Pharmaceuticals, Inc.	*internaţional*	A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Dose-ranging Study of Vapendavir in Moderate to Severe Asthmatic Adults with Symptomatic Human Rhinovirus Infection	II	24		**25.02.2015**		**22.04.2015**	**02.02.2017**	
123	**SNP-S-01, (version 1.02, 26.05.2014 initial), version 1.04, dated 23.03.2015**	2014-002176-83	Nitropress® (sodium nitroprusside) 5% dextrose® (dextrose)	Nu	Da	*Afecţiuni ale sistemului nervos*	ClinRx Tangent Research SRL Paul George Radu E-mail: paul.radu@clinrxtangent.com	Clinrx Tangent Research	*internaţional*	A randomized trial administering Sodium Nitroprusside vs. placebo as add-on to antipsychotics in patients with schizophrenia	III	15		**01.04.2015**	**27.11.2014**		**21.10.2016**	
124	**2819-CL-0202, version 1.1, dated 05.06.2014**	2013-000508-40	fidaxomicin Dificlir® (fidaxomicin)	Vancomicina Hospira® (vancomycin hydrochloride) Vancomycin Capsules® (vancomycin hydrochloride)	Nu	*Infecţii bacteriene şi micoze*	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Astellas Pharma Europe B.V.	*internaţional*	A Phase 3, Multicenter, Investigator-blind, Randomized, Parallel Group Study to Investigate the Safety and Efficacy of Fidaxomicin Oral Suspension or Tablets Taken q12h, and Vancomycin Oral Liquid or Capsules Taken q8h, for 10 Days in Pediatric Subjects with Clostridium difficile-associated Diarrhea	III	22		**15.04.2015**		**28.05.2015**		
125	**CQBM076X2203, version 04, dated 07.07.2014**	2012-005615-92	QBM076	Nu	Da	*Afecţiuni ale tractului respirator*	Novartis Pharma Services Romania SRL Alexandru Ionel E-mail: alexandru.ionel@novartis.com	Novartis Pharma Services AG	*internaţional*	A two part, double blind, placebo controlled, study to assess the safety, tolerability, pharmacokinetics and pharmacodynamic effects of multiple doses of QBM076 in patients with COPD	II	25		**22.10.2014**		**17.03.2015**	**20.05.2015**	**13.05.2015**
126	**MYL-GAI-3001, version 2.0, dated 16.04.2014 VHP201469**	2014-000747-32	Basalog® (insulin glargine)	Lantus SoloStar® (insulin glargine)	Nu	*Afecţiuni nutriţionale şi metabolice*	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	MYLAN GmbH	*internaţional*	An Open-label, Randomized, Multi-center, Parallel-Group Clinical Trial Comparing the Efficacy and Safety of Mylan's Insulin Glargine with Lantus® in Type 1 Diabetes Mellitus Patients	III	33		**10.09.2014**		**16.02.2015**	**07.07.2016**	
127	**156-13-210, Amendment 1, dated 31.03.2014**	2014-000226-38	tolvaptan	Nu	Da	*Afecţiuni şi anomalii congenitale, ereditare şi neonatale*	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Otsuka Pharmaceutical Development & Commercialization, Inc.	*internaţional*	A Phase 3b, Multi-center, Randomized-withdrawal, Placebo-controlled, Double-blind, Parallel-group Trial to Compare the Efficacy and Safety of Tolvaptan (45 to 120 mg/day, Split-dose) in Subjects with Chronic Kidney Disease Between Late Stage 2 to Early Stage 4 Due to Autosomal Dominant Polycystic Kidney Disease	III	15		**05.08.2015**		**09.09.2015**	**14.04.2017**	
128	**1409R2121, version 1, dated 25.03.2014**	2014-000914-76	S-649266	Zienam® (imipenem + cilastatin sodium)	Nu	*Infecţii bacteriene şi micoze*	August Research SRL Andreea Catalina Stoenescu E-mail: cstoenescu@augustresearch.com	Shionogi Inc.	*internaţional*	A Multicenter, Double-blind, Randomized, Clinical Study to Assess the Efficacy and Safety of Intravenous S-649266 in Complicated Urinary Tract Infections with or without Pyelonephritis or Acute Uncomplicated Pyelonephritis Caused by Gram-Negative Pathogens in Hospitalized Adults in Comparison with Intravenous Imipenem/Cilastatin	II	30		**30.06.2015**			**16.08.2016**	
129	**CLCZ696D2301, version 01, dated 10.06.2014**	2013-001747-31	LCZ696	Diovan® (valsartan)	Da	*Afecţiuni cardiovasculare*	PAREXEL International Romania SRL Diana Campeanu E-mail: Europe.CTA@Novartis.com	Novartis Pharma services AG	*internaţional*	A multicenter, randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared to valsartan, on morbidity and mortality in heart failure patients (NYHA Class II-IV) with preserved ejection fraction	III	110		**29.04.2015**		**20.05.2015**		

130	**CTT116853, version 00, dated 22.04.2014 VHP201449**	2013-003073-10	fluticasone furoate + umeclidinium bromide + vilanterol trifenatate (combinatie)	Symbicort Turbohaler® (budesonide + formoterol fumarate)	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Roxana Georgeta Gheorghiu E-mail:roxana.d.gheorghiu@gsk.com	GlaxoSmithKline Research and Development Ltd	internaţional	A Phase III, 24 week, randomized, double blind, double dummy, parallel group study (with an extension to 52 weeks in a subset of subjects) comparing the efficacy, safety and tolerability of the fixed dose triple combination FF/UMEC/VI administered once-daily in the morning via a dry powder inhaler with budesonide/formoterol 400mcg/12mcg administered twice-daily via a reservoir inhaler in subjects with chronic obstructive pulmonary disease	III	100		**22.10.2014**		**30.01.2015**	**07.04.2016**	
131	**1517-CL-0613, version 1.0, dated 30.06.2014**	2013-001497-16	roxadustat (FG-4592/ASP1517)	Aranesp® (darbepoetin alfa) Eprex® (epoetin alfa)	Nu	Afecţiuni limfatice şi ale sângelui	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Astellas Pharma Europe B.V.	internaţional	A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Roxadustat in the Maintenance Treatment of Anemia in End Stage Renal Disease Subjects on Stable Dialysis	III	140		**20.05.2015**		**08.06.2015**		
132	**CZOL446H2337, version 04, 16.08.2013**	2008-001252-52	Aclastal® (zoledronic acid)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Novartis Pharma Services Romania SRL Alexandru Ionel E-mail: alexandru.ionel@novartis.com	Novartis Pharma Services AG	internaţional	A multicenter, randomized, double-blind, placebo controlled efficacy and safety trial of intravenous zoledronic acid twice yearly compared to placebo in osteoporotic children treated with glucocorticoids	III	3		**14.08.2015**				
133	**CLDK378A2301, version 01, dated 27.08.2013**	2013-000319-26	LDK378	Alimta® (pemetrexed) Carboplatin® (carboplatin) Cisplatin® (cisplatin)	Nu	Afecţiuni oncologice	Clinical Trial Center S.R.L Selena Anita Gais E-mail: selena.boghiu@clinicaltrial.ro	Novartis Pharma Services AG	internaţional	A phase III multicenter, randomized study of oral LDK378 versus standard chemotherapy in previously untreated adult patients with ALK rearranged (ALK-positive), stage IIIB or IV, non-squamous non-small cell lung cancer	III	25		**19.02.2015**			**26.03.2015**	
134	**001CTFITERMAN**	2014-003188-39	SINDOLOR gell® (piroxicam + clobenzaprina clorhidrat + lidocaina)	Nu	Nu	Afecţiuni ale sistemului musculo-scheletic	FITERMAN PHARMA Emanuel Hanus E-mail: emanuel.hanus@fitermanpharma.ro	FITERMAN PHARMA	naţional	Eficacitatea Sindolor gel ca analgezic local în procedura de litotiţie extracorporeală	III	300						
135	**CF102-201HCC, (Amendment 1, dated 16.06.2014 initial), Amendment 2, dated 08.10.2014**	2014-000489-23	CF102	Nu	Da	Afecţiuni oncologice	CTG Cardiomed CRO Iuliana Mihaela Cojocaru E-mail: iuliana.cojocaru@ctgcro.com	CanFite BioPharma Ltd.	internaţional	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of CF102 in the Second-Line Treatment of Advanced Hepatocellular Carcinoma in Subjects with Child-Pugh Class B Cirrhosis	II	33		**27.04.2015**	**29.10.2014**	**26.05.2015**		
136	**CNTO136ARA3004, Amendment 02, dated 01.05.2014**	2012-001176-10	sirukumab (CNTO136)	Nu	Da	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Janssen-Cilag International N.V.	internaţional	A Multicenter, Parallel-group Study of Long-term Safety and Efficacy of CNTO 136 (sirukumab) for Rheumatoid Arthritis in Subjects Completing Treatment in Studies CNTO136ARA3002 (SIRROUND-D) and CNTO136ARA3003 (SIRROUND-T)	III	45		**24.06.2015**	**05.02.2015**	**10.11.2015**		
137	**D589SC00003, version 1.0, dated 23.06.2014**	2013-004473-28	Symbicort Turbuhaler® (budesonide + formoterol fumarate)	terbutaline sulfate Pulmicort Turbuhaler® (budesonide)	Da	Afecţiuni ale tractului respirator	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A 52-week, double-blind, randomised, multi-centre, phase III, parallel-group study in patients 12 years and older with asthma, evaluating the efficacy and safety of Symbicort (budesonide/formoterol) Turbuhaler 160/4.5 µg 'as needed' compared with Pulmicort (budesonide) Turbuhaler 200 µg twice daily plus terbutaline Turbuhaler 0.4 mg 'as needed'	III	1482		**03.04.2015**				
138	**FKB327-002, version final, dated 25.04.2014**	2014-000109-11	FKB327 (adalimumab)	Humira® (adalimumab)	Da	Afecţiuni ale sistemului imunitar	CEBIS International SRL Mihai Ioan Manolache E-mail:office@cebis-int.com	Fujifilm Kyowa Kirin Biologics Co., Ltd.	internaţional	A Randomised, Blinded, Active-Controlled Study to Compare FKB327 Efficacy and Safety with the Comparator Humira® in Rheumatoid Arthritis Patients Inadequately Controlled on Methotrexate	III	54		**20.04.2015**		**28.05.2015**	**12.07.2016**	
139	**GS-US-330-1401, version Original, dated 24.03.2014**	2014-001011-39	GS-4774 Viread® (tenofovir disoproxil fumarate)	Nu	Nu	Afecţiuni virale	PRA Romania SRL Oana David E-mail:davidoana@prahs.com	Gilead Sciences, Inc.	internaţional	A Phase 2, Randomized, Open-Label Study to Evaluate the Safety and Efficacy of GS-4774 in combination with Tenofovir Disoproxil Fumarate (TDF) for the Treatment of Subjects with Chronic Hepatitis B and who are currently not on Treatment	II	10		**20.03.2015**	**11.12.2014**	**13.05.2015**		
140	**GTI130S, version 2.0, dated 19.06.2014**	2013-005098-28	Gamunex® (human immune globulin)	Nu	Nu	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Grifols Therapeutics Inc.	internaţional	A multicenter, prospective, open-label, non-controlled clinical trial to assess the efficacy and safety of Immune Globuline (Human), 10% Caprylate/Chromatography Purified (IGIV-C) in patients with Myasthenia Gravis exacerbations	III	10		**21.07.2015**	**05.03.2015**	**08.02.2016**		
141	**000134, dated 13.02.2014**	2014-000627-24	Zomacton® (somatropin)	Genotropin® (somatropin)	Nu	Afecţiuni hormonale	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Ferring Pharmaceuticals A/S	internaţional	A follow-up study to examine the presence of anti-human growth hormone antibodies following a randomised, open-label, parallel-group, multi-centre trial (FE 999905 CS07) in which the efficacy and safety of 12 months' treatment with one daily dose of ZOMACTON were compared to one daily dose of GENOTROPIN	III	1		**11.03.2015**		**23.04.2015**	**17.08.2015**	
142	**M14-347, Amendment 1, dated 12.05.2014 VHP2013134**	2013-004034-15	Humira® (adalimumab)	Nu	Nu	Afecţiuni ale sistemului digestiv	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Multicenter, Open-Label Study to Evaluate the Long Term Efficacy, Safety, and Tolerability of Repeated Administration of Adalimumab in Subjects with Crohn's Disease	III	21		**18.09.2014**	**15.06.2015**		**19.09.2016**	

143	**TR02, (version 4.0, dated 24.06.2014 initial), version 6.0, dated 10 October 2014**	2013-005625-22	nalbuphine hydrochloride	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Trevi Therapeutics, Inc.	internaţional	A Randomized, Double-Blind, Placebo-Controlled, Parallel, 3-Arm Study of the Safety and Anti-Pruritic Efficacy of Nalbuphine HCL ER Tablets in Hemodialysis Patients with Uremic Pruritis	II/III	73		**03.12.2014**	**05.11.2014**	**11.12.2014**	**08.06.2015**	
144	**TR02ext, version 2.0, dated 24.06.2014**	2013-005626-29	nalbuphine hydrochloride	Nu	Nu	Afecţiuni ale pielii şi ţesutului conjunctiv	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Trevi Therapeutics, Inc.	internaţional	An Open Label Extension Study of the Safety and Anti-Pruritic Efficacy of Nalbuphine HCL ER Tablets in Hemodialysis Patients with Uremic Pruritus	II/III	59		**05.02.2015**	**24.11.2014**	**10.03.2015**	**24.11.2016**	
145	**DICL001, version 1.6, dated 19.05.2014**	2014-002279-27	Diclofenac Sodium Topical Gel 1%® (diclofenac sodium)	Voltaren® Gel (diclofenac sodium)	Da	Afecţiuni ale sistemului musculo-scheletic	AS Egeen Cosmin Bacanu E-mail: cosmin.bacanu@egeeninc.com	Hi-Tech Pharmacal Co., Inc.	internaţional	A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Three-Arm, Multi-Site Study to Evaluate the Clinical Equivalence of Diclofenac Sodium Topical Gel 1% (Hi-Tech Pharmacal Co., Inc.) with Voltaren® Gel (Diclofenac Sodium Topical Gel) 1%(Novartis) in Patients with Osteoarthritis of the Knee	III	150		**06.03.2015**		**03.09.2015**	**01.04.2016**	
146	**BBI608-336, Amendment 4, dated 05.08.2014**	2014-000774-18	napabucasin (BBI608)	Paclitaxel® (paclitaxel)	Da	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail:andreea-raluca.ghinea@parexel.com	Boston Biomedical, Inc.	internaţional	A Phase III Randomized, Double-Blind, Placebo-Controlled Clinical Trial of BBI608 plus Weekly Paclitaxel vs. Placebo plus Weekly Paclitaxel in Adult Patients with Advanced, Previously Treated Gastric and Gastro-Esophageal Junction Adenocarcinoma	III	26		**10.06.2015**		**23.07.2015**		
147	**RIVAROXDVT3002/BAY59-7939/17261, (Amendment INT-2, dated 11.04.2014 initial), Amendment INT-4, dated 19.01.2015**	2014-000305-13	rivaroxaban	Nu	Da	Afecţiuni cardiovasculare	S.C. BAYER S.R.L. Corina Carpa-veche E-mail:corina.carpa-veche@bayer.com	Janssen-Cilag International NV	internaţional	Medically Ill Patient Assessment of Rivaroxaban Versus Placebo IN Reducing Post-Discharge Venous Thrombo-Embolism Risk (MARINER)	III	113		**25.03.2015**		**29.04.2015**		
148	**NN8640-4054, version 2.0, dated 04.07.2014**	2013-002892-16	NNC0195-0092 PDS290	Norditropin FlexPro® (somatropin)	Da	Afecţiuni hormonale	Novo Nordisk Farma SRL Catalin Bucerzan E-mail:catb@novonordisk.com	Novo Nordisk A/S	internaţional	A multicentre, multinational, randomised, parallel-group, placebo-controlled (double blind) and active-controlled (open) trial to compare the efficacy and safety of once weekly dosing of NNC0195-0092 with once weekly dosing of placebo and daily Norditropin® FlexPro® in adults with growth hormone deficiency for 35 weeks, followed by a 53-week open-label extension period	III	21		**22.12.2014**		**13.02.2015**		
149	**A3921187, version Final, dated 26.08.2014 VHP201471**	2014-000358-13	tofacitinib citrate (CP-690, 550-10)	Humira® (adalimumab) Methotrexate sodium® (methotrexate sodium)	Da	Afecţiuni ale sistemului imunitar	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Pfizer Inc., New York	internaţional	A phase 3b/4 randomized double blind study of 5 mg of Tofacitinib with and without Methotrexate in comparison to Adalimumab with Methotrexate in subjects with moderately to severely active rheumatoid arthritis	II/IIV	77		**03.10.2014**	**10.11.2014**	**28.01.2015**	**16.12.2016**	
150	**RPC01-301, version 2.0, dated 26.08.2014**	2014-002320-27	ozanimod (RPC1063)	Avonex® (interferon beta-1A)	Da	Afecţiuni ale sistemului nervos	PSI Pharma Support Romania SRL Mihaela David E-mail:mihaela.david@psi-cro.com	Celgene International II Sàrl (CIS II)	internaţional	A Phase 3, multi-center, randomized, Double-Blind, double-dummy, active controlled, parallel group study to evaluate the efficacy and safety of RPC1063 administered orally to relapsing multiple sclerosis patients	III	36		**25.03.2015**	**14.01.2015**	**05.05.2015**	**22.12.2016**	
151	**PIX306, version A.8 Non-NA, dated 25.07.2014**	2012-001790-86	Pixuvri® (pixantrone) rituximab	gemcitabine rituximab	Nu	Afecţiuni oncologice	PSI Pharma Support Romania SRL Mihaela David E-mail:mihaela.david@psi-cro.com	CTI Biopharma, Corp.	internaţional	A Randomized Multicenter Study Comparing Pixantrone + Rituximab with Gemcitabine + Rituximab in Patients with Aggressive B-cell Non-Hodgkin Lymphoma Who Have Relapsed after Therapy with CHOP-R or an Equivalent Regimen and are Ineligible for Stem Cell Transplant	III	16		**23.04.2015**	**18.12.2014**	**24.06.2015**		
152	**MK-3475-045, version 02, dated 26.08.2014**	2014-002009-40	pembrolizumab (MK-3475)	Paclitaxel® (paclitaxel) Javlor® (vinflunine) Docetaxel® (docetaxel)	Nu	Afecţiuni oncologice	Merck Sharp and Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III Randomized Clinical Trial of Pembrolizumab (MK-3475) versus Paclitaxel, Docetaxel or Vinflunine in Subjects with Recurrent or Progressive Metastatic Urothelial Cancer	III	20	5	**18.06.2015**	**15.06.2015**	**22.07.2015**		**02.03.2016**
153	**MRZ60201_3091_1, version 1.0, dated 17.07.2014**	2013-004532-30	Xeonim® (botulinum toxin type A)	Nu	Da	Afecţiuni ale sistemului nervos	Pharm-Olam International (UK) Ltd., Representative Office for Romania Cătălina Teodor E-mail: catalina.teodor@pharm-olam.com	Merz Pharmaceuticals GmbH	internaţional	Prospective, randomized, double-blind, placebo-controlled, parallel-group, multicenter study with an open-label extension period to investigate the efficacy and safety of NT 201 in the treatment of children and adolescents (2–17 years) with chronic troublesome sialorrhea associated with neurological disorders, and/or intellectual disability	III	15		**22.02.2016**	**02.04.2015**		**21.02.2017**	
154	**XM02-ONC-201, dated 12.05.2014**	2014-001772-55	Tevagrastim® (filgrastim)	Nu	Nu	Afecţiuni oncologice	Pharmaceutical Research Associates Romania SRL Oana David E-mail:davidoana@prahs.com	TEVA Pharmaceutical Industries Ltd	internaţional	A Multicenter, Open-Label Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, Efficacy, and Immunogenicity of Daily Subcutaneous Administration of 5 µg/kg tbo-filgrastim in Infants, Children and Adolescents with Solid Tumors without Bone Marrow Involvement	II	10		**29.05.2015**	**19.03.2015**	**12.08.2015**	**03.04.2017**	
155	**1218.149, version 1.0, dated 15.05.2014**	2014-000904-88	Trajenta® (linagliptin)	Nu	Da	Afecţiuni nutriţionale şi metabolice	SC DOKUMEDS CRO SRL Luminiţa Neferu E-mail: luminita.neferu@dokumeds.com	Boehringer Ingelheim International GmbH	internaţional	A 24 week randomized, double-blind, placebo-controlled, parallel group, efficacy and safety trial of once daily linagliptin, 5 milligrams orally, as add on to basal insulin in elderly Type 2 Diabetes Mellitus patients with insufficient glycaemic control	IV	110		**27.04.2015**	**16.03.2015**		**02.09.2016**	

156	**2819-MA-1002, version 1, dated 06.06.2014**	2013-004619-31	Difficlir® (fidaxomicin)	Vancomycin® (vancomycin)	Nu	Infecţii bacteriene şi micoze	ClinTec International Ltd. Constantin Nedescu E-mail: cnedescu@clintec.com	Astellas Pharma Europe Ltd.	internaţional	A phase IIIb/IV randomized, controlled, open label, parallel group study to compare the efficacy of vancomycin therapy to extended duration fidaxomicin therapy in the sustained clinical cure of Clostridium difficile Infection in an older population	IV	50		**10.06.2015**	**23.04.2015**		**05.05.2016**	
157	**M14-423, (Protocol Amendment 1, dated 26.06.2014 initial), Protocol Amendment 2, dated 19.01.2015**	2014-001022-14	ABT-450 + ritonavir + ABT-267 (ombitasvir) ABT-333 (dasabuvir) ribavirin	Nu	Nu	Afecţiuni virale	PPD Romania S.R.L Cristina Voicu E-mail: cristina.voicu@ppdi.com	AbbVie Deutschland GmbH & Co. KG	internaţional	An Open-Label, Multicenter Study to Evaluate Long-Term Outcomes with ABT-450/Ritonavir/ABT-267 (ABT-450/r/ABT-267) and ABT-333 With or Without Ribavirin (RBV) in Adults With Genotype 1 Chronic Hepatitis C Virus (HCV) Infection	III	50		**08.05.2015**	**19.02.2015**			
158	**156-13-211, Administrative Change 1, dated 05.09.2014**	2014-001516-19	tolvaptan (OPC-41061)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Otsuka Pharmaceutical Development & Commercialization	internaţional	A Phase 3b, Multi-center, Open-label Trial to Evaluate the Long Term Safety of Immediate-release Tolvaptan (OPC-41061, 30 mg to 120 mg/day, Split dose) in Subjects with Autosomal Dominant Polycystic Kidney Disease	III	23		**05.08.2015**				
159	**ARN-509-003, Amendment INT-5, dated 01.07.2014**	2012-004322-24	ARN-509	Nu	Da	Afecţiuni oncologice	Pharmaceutical Research Associates Romania SRL Oana David E-mail: davidoana@prahs.com	Aragon Pharmaceuticals, Inc	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase III Study of ARN-509 in Men with Non-Metastatic (M0) Castration-Resistant Prostate Cancer	III	20		**08.05.2015**	**23.02.2015**	**20.08.2015**		
160	**ABR49490, (version 1.8, dated 22.09.2014 initial), version 1.9, dated 24.03.2015 (Romania)**	2014-002765-30	Abilify Maintena® Xeplion®	Abilify® Invega®	Nu	Afecţiuni ale sistemului nervos	CliniRx Tangent Research SRL Paul George Radu E-mail: paul.radu@clinirxtangent.com	EGRIS	internaţional	European Long-acting Antipsychotics in Schizofrenia Trial EULAST	IV	30		**01.04.2015**				
161	**D5160C00007, version 1.0, dated 08.08.2014**	2014-002694-11	AZD9291	Iressa® (gefitinib) Tarceva® (erlotinib)	Da	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Cristina Manoliu E-mail: cristina.manoliu@parexel.com	AstraZeneca AB	internaţional	A phase III, double-blind, randomised study to assess the efficacy and safety of AZD9291 versus a standard of care Epidermal Growth Factor Receptor Tyrosine Kinase Inhibitor as first-line treatment in patients with Epidermal Growth Factor Receptor Mutation Positive, locally advanced or Metastatic Non-Small Cell Lung Cancer	III	21		**19.02.2015**	**05.03.2015**	**30.04.2015**		
162	**D5010C00009 (IBD-MC-AZES), (version 02, dated 03.09.2014 initial), version 04, dated 12.03.2015**	2014-002601-38	AZD3293	Nu	Da	Afecţiuni ale sistemului nervos	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail:andreea-raluca.ghinea@parexel.com	Eli Lilly and Company	internaţional	A 24-Month, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group, Efficacy, Safety, Tolerability, Biomarker and Pharmacokinetics Study of AZD3293 in Early Alzheimer's Disease (The AMARANTH Study)	II/III	50		**30.07.2015**	**05.03.2015**			
163	**CNTO148PSA3001, Amendment 1, dated 05.08.2014**	2014-000242-30	golimumab	Nu	Da	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail:andreea-raluca.ghinea@parexel.com	Janssen Biologics, BV	internaţional	A Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Golimumab, an Anti-TNFα Monoclonal Antibody, Administered Intravenously, in Subjects with Active Psoriatic Arthritis	III	56		**30.07.2015**		**31.08.2016**	**22.03.2017**	
164	**IG1104, version 2.1, dated 02.07.2014**	2013-004503-39	Flebogamma DIF® (human normal immunoglubulinIVIg)	Nu	Da	Afecţiuni ale sistemului nervos	EastHORN Clinical Services in CEE Anca Brașoveanu E-mail: anca.brasoveanu@easthorn.eu	Instituto Grifols, S.A.	internaţional	A multicenter, prospective, randomized, placebo-controlled, double-blind, parallel-group clinical trial to assess the efficacy and safety of Immune Globulin Intravenous (Human) Flebogamma® 5% DIF in patients with Post-Polio Syndrome	II/III	10		**27.04.2015**	**05.02.2015**		**10.11.2016**	
165	**D3250C00021, version 1.0, dated 13.08.2014**	2014-001086-27	benralizumab (MEDI-563)	Nu	Da	Afecţiuni ale tractului respirator	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A Multicenter, Double-blind, Randomized, Parallel Group, Phase 3 Safety Extension Study to Evaluate the Safety and Tolerability of Benralizumab (MEDI-563) in Asthmatic Adults and Adolescents on Inhaled Corticosteroid Plus Long-acting β2 Agonist (BORA)	III	55		**30.06.2015**				
166	**CONTINUATION-PV, version 1.0, dated 03.06.2014**	2014-001357-17	AOP2014 (Pegylated proline-interferon alpha-2b recombinant)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	PSI Pharma Support Romania SRL Mihaela David E-mail:mihaela.david@psi-cro.com	AOP Orphan Pharmaceuticals AG	internaţional	An open-label, multicenter, phase II/b study assessing the long-term efficacy and safety of AOP2014 in patients with Polycythemia Vera who previously participated in the PROUD-PV study	III	8		**19.03.2015**	**11.02.2015**	**30.03.2015**		
167	**201378, (version 00, dated 01.09.2014 initial), Amendment 02, dated 29.01.2015**	2014-002253-19	Relvar Ellipta® (fluticasone furoate + vilanterol)	Seretide Accuhaler® (fluticasone propionate + salmeterol) Flixotide Accuhaler® (fluticasone propionate)	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Ana Magherusan E-mail: ana.l.magherusan@gsk.com	GlaxoSmithKline Research and Development Ltd	internaţional	A randomized, double-blind, double-dummy, parallel group, multicenter study of once daily Fluticasone Furoate/Vilanterol 100/25 mcg Inhalation Powder, twice daily Fluticasone Propionate/Salmeterol 250/50 mcg Inhalation Powder, and twice daily Fluticasone Propionate 250 mcg Inhalation Powder in the treatment of persistent asthma in adults and adolescents already adequately controlled on twice-daily inhaled corticosteroid and long-acting beta2 agonist	III	120		**08.05.2015**	**08.04.2015**	**20.05.2015**	**25.11.2016**	
168	**KKL172014, version 1.2, dated 20.10.2014**	2014-003470-17	Norvasc® (amlodipine besilate) olmesartan medoxomil + amlodipine besilate	Olmetec® (olmesartan medoxomil) Norvasc® (amlodipine besilate)	Da	Afecţiuni cardiovasculare	Verum Trialuri Clinice Ro SRL Laurenţiu Nedelcu E-mail: verum@verum.ro	Krka, d.d. Novo mesto	internaţional	The efficacy and safety of olmesartan medoxomil/amlodipine fixed combination in patients with grade 1 to grade 2 arterial hypertension. An international randomized, double-blind, 10-week multi-factorial clinical study	III	100		**27.02.2015**	**15.01.2015**	**16.03.2015**	**10.10.2015**	

169	**TRx-237-020, version 1.1, dated 11.06.2014**	2014-002013-37	leuco-methylthioninium bis(hydromethanesulfonate) (LMTM/TRx0237)	Nu	Nu	Afecţiuni ale sistemului nervos	Worldwide Clinical Trials Ltd E-mail:maciej.parowicz@wwctrials.com	TauRx Therapeutics Ltd	internaţional	An Open-Label, Extension Study of the Effects of Leuco-methylthioninium bis(hydromethanesulfonate) in Subjects with Alzheimer's Disease or Behavioral Variant Frontotemporal Dementia	III	3		**15.07.2015**		**28.09.2015**	**03.03.2017**	
170	**BO25323, version 2, dated 21.10.2014 VHP201495**	2014-001810-24	GDC-0199 (ABT-199) Gazyvaro® (obinutuzumab)	Chlorambucil® (chlorambucil)	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A Prospective, Open-Label, Multicenter Randomized Phase III Trial to Compare the Efficacy and Safety of a Combined Regimen of Obinutuzumab and Venetoclax (GDC-0199/ABT-199) versus Obinutuzumab and Chlorambucil in Previously Untreated Patients with CLL and Coexisting Medical Conditions	III	30		**26.11.2014**				
171	**TP0503, version 2.0, dated 13.05.2014**	2013-000366-11	TP05 (mesalazine)	Asacol® (mesalazine)	Da	Afecţiuni ale sistemului digestiv	Robarts Clinical Trials BV Tanja van Viegen E-mail: Tanja.vanviegen@robartsinc.com	Tillotts Pharma AG	internaţional	A Randomised Active-Controlled Double-Blind and Open Label Extension Study to Evaluate the Efficacy, Long-term Safety and Tolerability of TP05 3.2 g/day for the Treatment of Active Ulcerative Colitis (UC)	III	50		**25.03.2015**	**07.01.2015**	**22.06.2015**	**17.05.2016**	
172	**DS5565-A-E311, version 2.0, dated 29.07.2014**	2013-005163-10	mirogabalin (DS-5565)	Lyrica® (pregabalin)	Da	Afecţiuni sistemului nervos	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@iNCResearch.com	Daiichi Sankyo, Inc. United States	internaţional	A Randomized, Double-Blind, Placebo- and Active-Controlled Study of DS-5565 in Subjects with Pain Associated with Fibromyalgia	III	60		**12.06.2015**	**04.03.2015**		**07.07.2016**	
173	**DS5565-A-E312, version 2.0, dated 31.07.2014**	2013-005164-26	mirogabalin (DS-5565)	Nu	Nu	Afecţiuni sistemului nervos	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@iNCResearch.com	Daiichi Sankyo Development Ltd	internaţional	An Open-Label Extension Study of DS-5565 for 52 Weeks in Pain Associated with Fibromyalgia	III	12		**12.06.2015**	**04.03.2015**		**19.04.2017**	
174	**MW2012-01-01, version 5, dated 08.09.2014**	2014-003066-24	NexoBrid® (concentrate of proteolytic enzymes enriched in bromelain)	Nu	Nu	Leziuni, intoxicaţii şi afecţiuni profesionale	Rotrial Contract Research SRL Greta Paun E-mail: greta_paun@rotrial.ro	MediWound Ltd.	internaţional	A multicenter, multinational, randomized, controlled, open label study, performed in children with thermal burns, to evaluate the efficacy and safety of NexoBrid as compared to standard of care (SOC) treatment	III	35		**01.04.2015**	**23.03.2015**	**07.12.2015**		
175	**54767414MMY3007, (version initial, dated 26.06.2014 initial), INT-1, dated 24.11.2014**	2014-002272-88	daratumumab (HuMax-CD38)	Nu	Nu	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail:andreea-raluca.ghinea@parexel.com	Janssen-Cilag International N.V.	internaţional	A Phase 3, Randomized, Controlled, Open-label Study of VELCADE (Bortezomib) Melphalan-Prednisone (VMP) Compared to Daratumumab in Combination with VMP (D-VMP), in Subjects with Previously Untreated Multiple Myeloma who are Ineligible for High-dose Therapy	III	17		**30.07.2015**		**15.08.2015**		
176	**D5553C00002, version 1, dated 03.10.2014**	2014-003502-33	Bydureon® (exenatide)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	AstraZeneca AB	internaţional	A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel group, Phase 3 Trial to Evaluate the Safety and Efficacy of Once Weekly Exenatide Therapy Added to Titrated Basal Insulin Glargine Compared to Placebo Added to Titrated Basal Insulin Glargine in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Basal Insulin Glargine with or without Metformin	III	58		**24.06.2015**		**09.07.2015**	**19.08.2016**	
177	**MB102-229, version original, dated 10.09.2014**	2013-004674-97	dapagliflozin (BMS-512148)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	AstraZeneca AB	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of Dapagliflozin as an Add-on to Insulin Therapy in Subjects with Type 1 Diabetes Mellitus	III	60		**27.05.2015**	**16.02.2015**	**25.06.2015**		
178	**MK-1439-018, (version 00, dated 01.08.2014 initial), Amendment 02, dated 10.02.2015**	2014-001127-69	doravirine (MK-1439)	Prezista® (darunavir) Norvir® (ritonavir)	Da	Afecţiuni virale	PAREXEL International Romania s.r.l. Cristina Stancu E-mail: Cristina.Stancu@parexel.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase 3 Multicenter, Double-Blind, Randomized, Active Comparator-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Doravirine (MK-1439) 100 mg Once Daily Versus Darunavir 800 mg Once Daily plus Ritonavir 100 mg Once Daily, Each in Combination with TRUVADA™ or EPZICOM™/KIVEXA™, in Treatment-Naïve HIV-1 Infected Subjects	III	18		**15.06.2015**	**19.03.2015**	**03.08.2015**		
179	**Rempex-505, (version 2.0, dated 06.08.2014 initial), version 3.0, dated 02.04.2015**	2014-000545-78	Carbavance® (meropenem/RPX7009)	Piperacillin/Tazobactam Teva®	Nu	Infecţii bacteriene şi micoze	August Research SRL Cătălina Stoenescu E-mail: cstoenescu@augustresearch.com	Rempex Pharmaceuticals, Inc.	internaţional	A phase 3, multi-center, randomized, double-blind, double-dummy study to evaluate the efficacy, safety, and tolerability of Carbavance™ (Meropenem/RPX7009) compared to Piperacillin/Tazobactam in the treatment of complicated urinary tract infections, including acute pyelonephritis, in adults	III	40		**28.09.2015**		**22.10.2015**	**28.04.2016**	
180	**ECRI-12-001, version 1.4, dated 10.09.2013**	2012-003515-58	Brilique® (ticagrelor) acetylsalicylic acid/aspirin	Brilique® (ticagrelor) acetylsalicylic acid/aspirin clopidogrel	Nu	Afecţiuni cardiovasculare	Clinical Research Associate InterEuropa Clinical Research BV Ioan Crisan E-mail:ioan.crisan@intereuropa.org	European Cardiovascular Research Institute	internaţional	GLOBAL LEADERS: Comparative effectiveness of 1 month of ticagrelor plus aspirin followed by ticagrelor monotherapy versus a current-day intensive dual antiplatelet therapy in all-comers patients undergoing percutaneous coronary intervention with bivalirudin and BioMatrix family drug-eluting stent use	III	1200						
181	**ISRCTN11225767, version 1.0, dated 26.11.2012**	2012-003192-19	Cyklokapron® (tranexamic acid)	Nu	Da	Afecţiuni ale sistemului digestiv	London School of Hygiene and Tropical Medicine Ian Roberts E-mail:crash.mail@lshtm.ac.uk	London School Of Hygiene and Tropical Medicine	internaţional	Tranexamic acid for the treatment of gastrointestinal haemorrhage: an international randomised, double blind placebo controlled trial	III	1000		**21.07.2015**				

182	**5172-017, (version 01, dated 19.10.2012 initial), version 02, dated 11.11.2014**	2012-002232-85	MK-5172	Nu	Nu	Afecţiuni virale	Merck Sharp and Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp	internaţional	A Long-Term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects With Chronic Hepatitis C Who Have Been Previously Treated with MK-5172 in a Prior Clinical Trial	II	16		**26.08.2015**		**09.09.2015**		
183	**AB12004, version 2.0, dated 12.03.2014**	2013-004162-34	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni oncologice	HT Research RO Cristina Dumbraveanu E-mail: cdumbraveanu@hungarotrial.com	AB Science	internaţional	A prospective, multicenter, randomized, double-blind, placebo-controlled, two-parallel groups, phase III study to compare the efficacy and safety of masitinib to placebo in patients with localized, primary Gastrointestinal Stromal Tumor (GIST) after complete surgery and with high risk of recurrence	III	20						
184	**156-08-276, Amendment 02, dated 19.05.2014**	2013-002005-59	tolvaptan (OPC-41061) Samsca® (tolvaptan)	Nu	Nu	Afecţiuni nutriţionale şi metabolice	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	Otsuka Pharmaceutical Development & Commercialization, Inc.	internaţional	A Phase 3b, Multicenter, Open-label, Randomized Withdrawal Trial of the Effects of Titrated Oral SAMSCA® (Tolvaptan) on Serum Sodium, Pharmacokinetics, and Safety in Children and Adolescent Subjects Hospitalized With Euvolemic or Hypervolemic Hyponatremia	III	8		**07.10.2015**	**06.07.2015**		**24.07.2017**	
185	**156-11-294, Amendment 01, dated 05.09.2014**	2013-002810-11	tolvaptan (OPC-41061) Samsca® (tolvaptan)	Nu	Nu	Afecţiuni nutriţionale şi metabolice	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	Otsuka Pharmaceutical Development & Commercialization, Inc.	internaţional	A Phase 3b, Multicenter, Extension Follow-up Trial to Evaluate the Long-term Safety of Children and Adolescent Subjects With Euvolemic or Hypervolemic Hyponatremia Who Have Previously Participated in a Trial of Titrated Oral SAMSCA® (Tolvaptan)	III	11		**07.10.2015**	**06.07.2015**			
186	**CLCZ696B2317, (version 00, dated 10.07.2014 initial), version 02, dated 28.04.2015**	2014-001971-30	LCZ696 (sacubitril/valsartan)	Nu	Nu	Afecţiuni cardiovasculare	PAREXEL International Romania SRL Andreea Fiechea E-mail: Europe.CTA@Novartis.com	Novartis Pharma services AG	internaţional	A multicenter study to evaluate safety and tolerability in patients with chronic heart failure and reduced ejection fraction from PARADIGM-HF receiving open label LCZ696	III	88		**22.10.2015**		**14.12.2015**		
187	**C1-3201, version 1.0, dated 03.09.2014**	2014-002839-33	Ruconest® (conestat alfa/rhC1INH)	Nu	Da	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Syncro Clinical Research Gabor Brok E-mail: gabor.brok@vlsworldwide.com	Pharming Group NV	internaţional	A Phase 2 Multicenter, Randomized, Double-Blind, Placebo-Controlled, 3-Period Crossover Study to Evaluate the Efficacy and Safety of Recombinant Human C1 Inhibitor in the Prophylaxis of Angioedema Attacks in Patients with Hereditary Angioedema (HAE)	II	5		**01.07.2015**	**15.06.2015**	**13.08.2015**	**03.05.2016**	
188	**CSL830_3002, version 1.0, dated 28.07.2014**	2014-001054-42	CSL830 (C1-esterase inhibitor)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	INC Research Romania Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	CSL Behring GmbH	internaţional	An open-label, randomized study to evaluate the long-term clinical safety and efficacy of subcutaneous administration of human plasma-derived C1-esterase inhibitor in the prophylactic treatment of hereditary angioedema	III	5		**20.05.2015**		**02.07.2015**	**20.07.2016**	
189	**RX-3341-303, (Amendment 2 (global), dated 09.05.2014 initial), Amendment 3 (global), dated 06.04.2015**	2014-004983-39	delafloxacin (RX-3341-83) vancomycin aztreonam	Da	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Melinta Therapeutics, Inc.	internaţional	A Phase 3, multicenter, randomized, double-blind, active-controlled study to evaluate the efficacy and safety of IV and oral delafloxacin compared with vancomycin + aztreonam in patients with acute bacterial skin and skin structure infections	III	55		**20.05.2015**	**04.03.2015**		**19.01.2016**	
190	**CC-486-NPC-001, (Amendment 1, dated 01.10.2014 initial), Amendment 2, dated 03.04.2015**	2014-001745-25	azacitidine (CC-486)	Nu	Nu	Afecţiuni oncologice	PPD Romania S.R.L. Ana-Maria Tanase E-mail: Ana.Tanase@ppdi.com	Celgene Corporation	internaţional	A Phase 2, Multicenter, International, 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	II	5		**31.07.2015**			**22.12.2015**	**18.08.2015**
191	**8-55-52930-309, Final Amendment 1, dated 19.11.2014**	2014-002389-62	lanreotide PRF	Nu	Nu	Afecţiuni hormonale	Chiltern International Limited Emilia Lungu E-mail: emilia.lungu@chiltern.com	Ipsen Group	internaţional	Phase IIA, open label, dose ascending study to determine the maximum tolerated dose, safety and tolerability, pharmacokinetics and pharmacodynamics of a single dose of lanreotide PRF in subjects with acromegaly previously treated and controlled with either octreotide LAR or lanreotide Autogel	II	1		**29.05.2015**	**02.04.2015**			**14.03.2016**
192	**1237.19, version 1.0, dated 29.09.2014**	2014-002275-28	tiotropium + olodaterol (combinaţie)	Spiriva Respimat® (tiotropium)	Nu	Afecţiuni ale tractului respirator	Pharm-Olam International (UK) Ltd., Representative Office for Romania Ramona Nicolescu E-mail: ramona.nicolescu@pharm-olam.com	Boehringer Ingelheim RCV GmbH & Co KG	internaţional	A randomised, double-blind, active-controlled parallel group study to evaluate the effect of 52 weeks of once daily treatment of orally inhaled tiotropium + olodaterol fixed dose combination compared with tiotropium on Chronic Obstructive Pulmonary Disease (COPD) exacerbation in patients with severe to very severe COPD. [DYNAGITO]	III	120		**31.07.2015**	**28.04.2015**	**26.08.2015**	**30.03.2017**	
193	**V1-03-2014, (version 1.0, dated 15.11.2014 initial), (version 2.0, data 05.05.2015), version 03, dated 11.09.2015**	2014-005038-77	Botox® (toxina botulinică)	Nu	Nu	Hiperactivitatea detrusorului de origine neurologică	SC Gnosis Evomed SRL Brândușa Ioana Bitel E-mail: brandusa.bitel@scala-cr.com	SC Gnosis Evomed SRL	naţional	A Phase III Comparative Study on the Duration of the Effect of Botulinum Toxin Intradetrusor Injections and Posterior Tibial Nerve Stimulation for the Hyperactive Neurogenic Detrusor	III	40		**12.02.2016**	**10.06.2015**		**15.06.2017**	
194	**CV181-363, version 1.0, dated 28.08.2014**	2014-001102-17	saxagliptin (BMS-477118-11) dapagliflozin (BMS-512148)	Januvia® (sitagliptin)	Da	Afecţiuni nutriţionale şi metabolice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	AstraZeneca AB	internaţional	A 26-week International, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3bTrial with a Blinded 26-week Long -term Extension Period to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin in Combination with Metformin Compared to Sitagliptin in Combination with Metformin in Adult Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Therapy Alone	III	60		**17.08.2015**	**19.03.2015**	**28.08.2015**	**26.10.2016**	

195	**MK-5172-077, version 00, dated 30.10.2014**	2014-003836-38	MK 5172A (MK-5172 + MK-8742)	Rebetol® (ribavirin) PegIntron® (pegylatenferon alfa-2b) Sovaldi® (sofosbuvir)	Nu	Afecţiuni virale	Merck Sharp and Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of MK-5172/MK-8742 versus Sofosbuvir/Pegylated Interferon/Ribavirin (PR) in Treatment-Naïve and PR Prior Treatment Failure Subjects with Chronic HCV GT1, 4 or 6 Infection	III	34		**12.02.2015**	**25.02.2015**	**12.03.2015**	**12.02.2016**	
196	**ALX0061-C201, version 1.0, dated 17.10.2014**	2014-003033-26	ALX-0061	Nu	Da	Afecţiuni ale sistemului imunitar	Worldwide Clinical Trials Limited Krina Shah E-mail: krina.shah@wwctrials.com	Ablynx NV	internaţional	A Phase IIb Multicenter, Randomized, Double-blind, Placebo-Controlled Dose-Range Finding Study of ALX-0061 Administered Subcutaneously in Combination with Methotrexate, in Subjects with Moderate to Severe Rheumatoid Arthritis Despite Methotrexate Therapy	II	23		**15.06.2015**			**08.08.2016**	
197	**CVT-301-005, version 2.0, dated 07.11.2014**	2014-003799-22	CVT-301 (levodopa)	Nu	Nu	Afecţiuni ale sistemului nervos	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Civitas Therapeutics, Inc.	internaţional	A Phase 3, Randomized Study Investigating the Safety of CVT-301 (Levodopa Inhalation Powder) in Parkinson's Disease Patients With Motor Response Fluctuations (OFF Phenomena) Compared to an Observational Cohort Control	III	28		**30.07.2015**		**09.09.2015**	**16.05.2017**	
198	**MIN-101C03, (version 1.2, dated 13.11.2014 initial), version 1.2, dated 13.11.2014 (Romania)**	2014-004878-42	MIN-101	Nu	Da	Afecţiuni ale sistemului nervos	CliniRx Tangent Research SRL Paul George Radu E-mail: paul.radu@clinirxtangent.com	Minerva Neurosciences, Inc.	internaţional	A Phase 2b, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of MIN-101 in Patients With Negative Symptoms of Schizophrenia, Followed by a 24-Week, Open-Label Extension	II	75		**20.04.2015**	**09.04.2015**	**28.05.2015**	**11.07.2016**	
199	**EFC13403, version 1, dated 10.11.2014**	2014-002844-42	SAR342434 (insulin lispro)	Humalog® (insulin lispro)	Nu	Afecţiuni nutriţionale şi metabolice	sanofi-aventis Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	Sanofi-aventis recherche et développement	internaţional	Six-month, Randomized, Open-label, Parallel-group Comparison of the Insulin Analog SAR342434 to Humalog® in Adult Patients With Type 2 Diabetes Mellitus also Using Insulin Glargine	III	35		**08.05.2015**			**16.02.2016**	
200	**EFC13799, (dated 13.10.2014 initial), version 1 (electronic 2.0), dated 13.10.2014**	2014-002399-10	HOE901 - U300 (insulin glargine)	Lantus SoloStar® (insulin glargine)	Nu	Afecţiuni nutriţionale şi metabolice	sanofi-aventis Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	Sanofi-aventis recherche & développement	internaţional	A Randomized, Open-label, 2-arm Parallel-group, Multicenter, 26-week Study Assessing the Safety and Efficacy of HOE901 U300 Versus Lantus in Older Patients with Type 2 Diabetes Inadequately Controlled on Antidiabetic Regimens Either Including no Insulin, or with Basal Insulin as Their Only Insulin	III	69		**31.07.2015**		**07.08.2015**		
201	**IM128-027, version Original, dated 20.08.2014 VHP2014112**	2014-002184-14	BMS-931699 (anti-CD28dab)	Nu	Da	Afecţiuni ale sistemului imunitar	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	A Phase 2, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of lulizumab pegol vs Placebo on a Background of Limited Standard of Care in the Treatment of Subjects with Active Systemic Lupus Erythematosus	II	35		**05.02.2015**	**16.02.2015**	**07.05.2015**		
202	**EFC14092, version 1 (electronic 1.0), dated 27.10.2014**	2014-002541-22	sarilumab (SAR153191, REGN88)	Humira® (adalimumab)	Da	Afecţiuni ale sistemului musculo-scheletic	sanofi-aventis Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	sanofi-aventis recherche & développement	internaţional	A randomized, double-blind, parallel-group study assessing the efficacy and safety of sarilumab monotherapy versus adalimumab monotherapy in patients with rheumatoid arthritis	III	1		**20.05.2015**				
203	**CA209172, (version Original, dated 18.04.2014 initial), version 03, dated 02.06.2015**	2014-001286-28	nivolumab (BMS-936558)	Nu	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	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 After Prior Treatment Containing an Anti-CTLA4 Monoclonal Antibody	II	4		**01.09.2015**	**27.04.2015**	**15.09.2015**		
204	**GO28399, version 3, dated 21.03.2014**	2012-003144-80	Zelboraf® (vemurafenib)	Nu	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffman-La Roche Ltd.	internaţional	An open-label, extension (rollover) study of vemurafenib in patients with BRAFV600 mutation-positive malignancies previously enrolled in an antecedent vemurafenib protocol	IV	5		**20.05.2015**	**12.03.2015**			
205	**CCD-05993AA1-08, version 1, dated 03.12.2014**	2014-001704-22	CHF 5993 pMDI (beclometasone dipropionate + formoterol fumarate + glycopyrronium bromide)	Ultibro Breezhaler® (indacaterol + glycopyrronium bromide)	Da	Afecţiuni ale tractului respirator	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Chiesi Farmaceutici S.p.A.	internaţional	A 52-week, Double Blind, Double dummy, Randomized, Multinational, Multicentre, 2-arm Parallel Group, active Controlled Clinical Trial of fixed combination of beclometasone dipropionate plus formoterol fumarate plus Glycopyrronium bromide administered via pMDI (CHF 5993) versus indacaterol/glycopyrronium (Ultibro®) via DPI in patients with Chronic Obstructive Pulmonary Disease	III	111		**12.05.2015**	**08.04.2015**	**29.05.2015**		
206	**CCD-05993AA1-07, version 1.0, dated 03.12.2014**	2014-001487-35	CHF 5993 pMDI (beclometasone dipropionate + formoterol fumarate + glycopyrronium bromide)	Relvar Ellipta® (fluticasone furoate + vilanterol trifenatate) Spiriva® (tiotropium bromide)	Nu	Afecţiuni ale tractului respirator	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Chiesi Farmaceutici S.p.A.	internaţional	A Multinational, Multicentre, Randomised, Open-Label, Active-Controlled, 26-Week, 2-Arm, Parallel Group Study to Evaluate the Non-Inferiority of Fixed Combination of Beclometasone Dipropionate Plus Formoterol Fumarate Plus Glycopyrronium Bromide Administered Via pMDI (CHF 5993) Versus Fixed Combination Of Fluticasone Furoate Plus Vilanterol Administered Via DPI (Relvar®) Plus Tiotropium Bromide (Spiriva®) for the Treatment of Patients With Chronic Obstructive Pulmonary Disease	III	95		**27.05.2015**	**08.04.2015**		**03.01.2017**	
207	**MK-3475-048, version 00, dated 05.12.2014**	2014-003698-41	pembrolizumab (MK-3475)	Carboplatin® (carboplatin) Fluorouracil-GRY® (fluorouracil) Erbitux® (cetuximab) Cisplatin® (cisplatin)	Nu	Afecţiuni oncologice	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a Subsidiary of Merck & Co. Inc.	internaţional	A Phase 3 Clinical Trial of Pembrolizumab (MK-3475) in First Line Treatment of Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma	III	12		**30.07.2015**	**17.08.2015**			**20.11.2015 02.03.2016**
208	**BAY59-7939/15786, version 2.0, dated 03.07.2014**	2012-004180-43	Xarelto® (rivaroxaban) rivaroxaban (BAY59-7939) Pantoprazole® (pantoprazole)	Aspirin® (aspirin/acetylasalicylic acid)	Da	Afecţiuni cardiovasculare	S.C. BAYER S.R.L. Corina Carpa-veche E-mail:ra_romania@bayer.com	Bayer AG (BAG)	internaţional	A randomized controlled trial of rivaroxaban for the prevention of major cardiovascular events in patients with coronary or peripheral artery disease (COMPASS - Cardiovascular OutcoMes for People using Anticoagulation StrategieS)	III	500		**04.05.2015**	**01.04.2015**	**27.05.2015**		

209	**APD811-003, Amendment 02, dated 15.08.2014**	2014-000667-40	ralinepag (APD811/AR392830)	Nu	Da	Afecţiuni cardiovasculare	Argint International Clinical Research & Development Services Kft. Teodora Dinu E-mail: teodora.dinu@argintInternational.com	Arena Pharmaceuticals, Inc.	internaţional	A Randomized, Double-blind, Parallel-group, Placebo-controlled Phase 2 Trial of APD811, an Oral IP Receptor Agonist, in Patients with Pulmonary Arterial Hypertension	II	16		**30.07.2015**	**21.05.2015**	**14.09.2015**	**22.06.2017**	
210	**APD811-007, Amendment 01, dated 15.08.2014**	2014-003042-27	ralinepag (APD811/AR392830)	Nu	Nu	Afecţiuni cardiovasculare	Argint International Clinical Research & Development Services Kft. Teodora Dinu E-mail: teodora.dinu@argintInternational.com	Arena Pharmaceuticals, Inc.	internaţional	An Open-Label Extension Study of APD811-003 in Patients with Pulmonary Arterial Hypertension	II	16		**30.07.2015**	**21.05.2015**	**07.03.2016**		
211	**MK-3475-059, version 02, dated 16.12.2014**	2014-003574-16	pembrolizumab (MK-3475)	Fluorouracil-GRY® (fluorouracil) Cisplatin® (cisplatin)	Nu	Afecţiuni oncologice	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a Subsidiary of Merck & Co., Inc.	internaţional	A Phase II Clinical Trial of Pembrolizumab as Monotherapy and in Combination with Cisplatin+5-Fluorouracil in Subjects with Recurrent or Metastatic Gastric or Gastroesophageal Junction Adenocarcinoma (KEYNOTE-059)	II	20		**29.05.2015**	**29.06.2015**	**20.10.2015**		**20.11.2015** **02.03.2016**
212	**FX006-2014-008, version 1.0, dated 14.11.2014**	2014-005329-11	triamcinolone acetonide (FX006)	Kenalog 40® (triamcinolone acetonide)	Da	Afecţiuni ale sistemului muscular şi scheletic	Nordic Bioscience Clinical Development Eugen Laurian Ştefănuţ E-mail: est@nordicbioscience.com	Flexion Therapeutics	internaţional	A Double-Blind, Randomized, Single-Dose Study to Assess the Safety and Efficacy of FX006 for the Treatment of Pain in Patients with Osteoarthritis of the Knee	III	50		**20.04.2015**			**21.01.2016**	
213	**ORTHO-2, version V1.5, dated 21.08.2013**	2012-002010-39	cultured mesenchymal cells from bone marrow isolation	Nu	Nu	Afecţiuni ale sistemului muscular şi scheletic	Universitatea de Medicină şi Farmacie "Victor Babeş" Timişoara Carmen Bunu Panaitescu E-mail: cbunu@umft.ro	Universidad Autónoma de Madrid	internaţional	Evaluation of safety and feasibility of bone marrow derived autologous MSCs to enhance bone healing in patients with avascular necrosis of femoral head	II	3		**03.04.2015**	**08.04.2015**			
214	**D5553C00003, version 1, dated 03.10.2014** **VHP2014120**	2014-003503-29	Bydureon® (exenatide) Forxiga® (dapagliflozin)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	AstraZeneca AB	internaţional	A 28-week, Multicenter, Randomized, Double-Blind, Active-Controlled, Phase 3 Study with a 24-week Extension Phase Followed by a 52-week Extension Phase to Evaluate the Efficacy and Safety of Simultaneous Administration of Exenatide Once Weekly 2 mg and Dapagliflozin Once Daily 10 mg Compared to Exenatide Once Weekly 2 mg Alone and Dapagliflozin Once Daily 10 mg Alone in Patients with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin	III	85		**11.03.2015**		**30.03.2015**		
215	**D5740C00001, version 4, dated 26.09.2014**	2014-000770-19	roxadustat (AZD9941)	Nu	Da	Afecţiuni cardiovasculare	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Roxadustat for the Treatment of Anemia in Chronic Kidney Disease Patients not on Dialysis	III	50		**27.08.2015**	**08.06.2015**	**26.09.2015**		
216	**ALX0061-C202, version 1.0, dated 17.10.2014**	2014-003012-36	ALX-0061	RoActemra® (tocilizumab)	Da	Afecţiuni ale sistemului imunitar	Worldwide Clinical Trials Ltd Geryl Steininger E-mail: geryl.steininger@wwctrials.com persoana de contact:Laura Mirela Neagu E-mail: laura.neagu@wwctrials.com	Ablynx NV	internaţional	A Phase IIb Multicenter, Randomized, Double-blind Study of ALX-0061 Administered Subcutaneously as Monotherapy, in Subjects with Moderate to Severe Rheumatoid Arthritis who are Intolerant to Methotrexate or for whom Continued Methotrexate Treatment is Inappropriate	II	13		**25.08.2015**			**19.07.2016**	
217	**GO29294, version 02, dated 14.01.2015** **VHP2014111**	2014-003231-19	MPDL3280A (RO5541267-F-03)	Javlor® (vinflunine) Docetaxel® (docetaxel) Paclitaxel® (paclitaxel)	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd.	internaţional	A phase III, open-label, multicenter, randomized study to investigate the efficacy and safety of Atezolizumab (ANTI-PD-L1 ANTIBODY) compared with chemotherapy in patients with locally advanced or metastatic urothelial bladder cancer after failure with platinum-containing chemotherapy	III	24		**12.03.2015**	**23.02.2015**	**29.04.2015**		
218	**M12-965, dated 25.09.2014** **VHP2014123**	2014-001471-31	ABT-122	Nu	Nu	Afecţiuni ale sistemului imunitar	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	Phase 2, Multicenter, Open-Label Extension (OLE) Study with ABT-122 in Rheumatoid Arthritis Subjects Who Have Completed the Preceding M12-963 Phase 2 Randomized Controlled Trial (RCT)	II	15		**27.02.2015**	**08.04.2015**		**23.05.2016**	
219	**GO29058, version 1, dated 13.10.2014** **VHP2014124**	2014-003185-25	taselisib (GDC-0032/RO 553-7381/F12) Faslodex® (fulvestrant)	Nu	Da	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A phase III, double-blind, placebo-controlled, randomized study of taselisib plus fulvestrant versus placebo plus fulvestrant in postmenopausal women with estrogen receptor-positive and HER2-negative locally advanced or metastatic breast cancer who have disease recurrence or progression during or after aromatase inhibitor therapy	III	36		**19.02.2015**	**26.03.2015**	**10.06.2015**		
220	**CSOM230C2413, version 00, dated 17.09.2014**	2014-002630-31	pasireotide (SOM230)	Nu	Nu	Afecţiuni hormonale	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A phase IIIb multicenter, open-label, single arm study to evaluate the efficacy and safety of pasireotide in patients with acromegaly inadequately controlled with first generation somatostatin analogues	III	8		**27.05.2015**		**28.09.2015**		
221	**D4280C00016, version 1, dated 14.01.2015**	2014-003244-13	ceftazidime avibactam (CAZ104)	Cefepim Rotexmedica®	Nu	Infecţii bacteriene şi micoze	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail: comesioana@prahs.com	AstraZeneca AB	internaţional	A single blind, randomised, multi-centre, active controlled, trial to evaluate safety, tolerability, pharmacokinetics and efficacy of ceftazidime and avibactam compared with cefepime in children from 3 months to less than 18 years of age with complicated urinary tract infections (cUTIs)	II	4		**17.09.2015**	**16.11.2015**	**07.09.2016**		

222	**GA29144, version 3, dated 09.12.2014**	2014-003824-36	etrolizumab (Ro 549-0261/F04-02)	Nu	Da	Afecţiuni ale sistemului digestiv	Roche Romania SRL Laura Colpcaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of Etrolizumab as an induction and maintenance treatment for patients with moderately to severely active Crohn's disease	III	5		**05.08.2015**	**28.05.2015**	**27.10.2015**		
223	**GA29145, version 2, dated 09.12.2014**	2014-003855-76	etrolizumab (Ro 549-0261/F04-02)	Nu	Nu	Afecţiuni ale sistemului digestiv	Roche Romania SRL Laura Colpcaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	An open-label extension and safety monitoring study of patients with moderately to severely active Crohn´s disease previously enrolled in the Etrolizumab phase III protocol GA29144	III	5		**17.08.2015**		**18.04.2016**		
224	**AI438-047/205888, version 1.0, dated 22.12.2014**	2014-002111-41	BMS-663068 BMS-663068/GSK3684934	Nu	Da	Afecţiuni virale	PPD Romania SRL Manuela Georgiana Botea E-mail: ManuelaGeorgiana.Botea@ppdi.com	ViiV Healthcare UK Limited	internaţional	A Multi-arm Phase 3 Randomized Placebo Controlled Double Blind Clinical Trial to Investigate the Efficacy and Safety of BMS-663068/GSK3684934 in Heavily Treatment Experienced Subjects Infected with Multi-drug Resistant HIV-1	III	50		**20.10.2015**	**11.06.2015**	**02.11.2015**		
225	**I4T-MC-JVDB, dated 30.01.2015**	2014-003791-23	Cyramza® (ramucirumab)	Nu	Nu	Afecţiuni oncologice	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company	internaţional	Randomized Phase 2 Trial Evaluating Pharmacokinetics and Safety of Four Ramucirumab Dosing Regimens in Second-Line Gastric or Gastroesophageal Junction Adenocarcinoma	II	14		**27.08.2015**	**25.06.2015**	**21.09.2015**		
226	**I4T-MC-JVDC, dated 14.01.2015**	2014-003655-66	Cyramza® (ramucirumab) docetaxel	Nu	Da	Afecţiuni oncologice	Eli Lilly Romania SRL Luminita Butnaru E-mail: butnaru_luminita@lilly.com	Eli Lilly and Company	internaţional	A Phase 3, 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 on or after Platinum-Based Therapy	III	12		**02.09.2015**		**26.10.2015**		
227	**D4280C00015, version 1, dated 20.01.2015**	2014-003242-28	ceftazidime avibactam (CAZ104)	Meronem® (meropenem)	Nu	Infecţii bacteriene şi micoze	Pharmaceutical Research Associates Romania SRL Oana David E-mail:davidoana@prahs.com	AstraZeneca AB	internaţional	A single blind, randomised, multi-centre, active controlled, trial to evaluate safety, tolerability, pharmacokinetics and efficacy of ceftazidime and avibactam when given in combination with metronidazole, compared with meropenem, in children from 3 months to less than 18 years of age with complicated intra-abdominal infections (cIAIs)	II	7		**17.09.2015**	**03.12.2015**	**01.04.2016**	**01.06.2017**	
228	**1423M0634, Edition 2, dated 03.02.2015**	2014-004942-91	lusutrombopag (S-888711)	Nu	Da	Afecţiuni limfatice şi ale sângelui	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Shionogi Ltd	internaţional	A Phase 3 Randomised, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of S-888711 (Lusutrombopag) for the Treatment of Thrombocytopenia in Patients with Chronic Liver Disease Undergoing Elective Invasive Procedures (L-PLUS 2)	III	12		**01.10.2015**		**28.01.2016**	**19.04.2017**	
229	**D4281C00001, Edition 3, dated 09.01.2015**	2012-004006-96	ceftazidime avibactam (CAZ-AVI)	meropenem	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	AstraZeneca AB	internaţional	A Phase III, Randomized, Multicentre, Double-blind, Double-dummy, Parallel-group Comparative Study to Determine the Efficacy, Safety And Tolerability of Ceftazidime-Avibactam (CAZ-AVI) Versus Meropenem in the Treatment of Nosocomial Pneumonia (NP) Including Ventilator Associated Pneumonia (VAP) in Hospitalised Adults	III	14		**08.07.2015**	**03.06.2015**	**18.09.2015**	**07.01.2016**	
230	**C-935788-048, version 3.0, dated 09.12.2014**	2013-005453-76	fostamatinib disodium (R935788)	Nu	Da	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	Rigel Pharmaceuticals, Inc.	internaţional	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	III	6		**20.10.2015**		**11.12.2015**	**31.08.2016**	
231	**CA209-238, version initial, dated 11.11.2014**	2014-002351-26	nivolumab (BMS-936558) ipilimumab (BMS-734016)	Nu	Da	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	A Phase 3, 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	III	50		**08.07.2015**	**22.06.2015**	**27.07.2015**		
232	**M13-740, Amendment 1, dated 19.02.2015 VHP2014130**	2014-003240-12	ABT 494	Nu	Da	Afecţiuni ale sistemului digestiv	Covance Clinical and Periapproval Services Limited Loredana Radulescu E-mail: Loredana.Radulescu@covance.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of ABT-494 for the Induction of Symptomatic and Endoscopic Remission in Subjects with Moderately to Severely Active Crohn's Disease who have Inadequately Responded to or are Intolerant to Immunomodulators or Anti-TNF Therapy	II	8		**02.04.2015**		**31.08.2015**		
233	**7655A-013, version 00, dated 07.01.2015**	2015-000066-62	imipenem/cilastatin + relebactam (MK-7655)	Primaxin® (imipenem/cilastatin) Colistimethate for Injection® (colistimethate sodium)	Da	Infecţii bacteriene şi micoze	Merck Sharp & Dohme Romania SRL Florina Prunaru E-mail: florina.prunaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Randomized, Double-Blind, Active Comparator-Controlled Clinical Trial to Estimate the Efficacy and Safety of Imipenem/Cilastatin/Relebactam (MK-7655A) Versus Colistimethate Sodium + Imipenem/Cilastatin in Subjects with Imipenem-Resistant Bacterial Infection	III	8		**27.11.2015**	**21.12.2015**	**05.07.2016**		
234	**CNTO1959PSA2001, Amendment 1, dated 05.02.2015**	2014-003697-17	guselkumab (CNTO1959) Stelara® (ustekinumab, CNTO1275)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Johnson & Johnson Romania SRL Irina Toma E-mail:itoma@its.jnj.com	Janssen-Cilag International N.V.	internaţional	A Phase 2a, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab in the Treatment of Subjects With Active Psoriatic Arthritis	II	7		**14.08.2015**	**24.06.2015**		**17.01.2017**	

235	**C-935788-049, version 3.0, dated 21.11.2014**	2013-005454-30	fostamatinib disodium (R935788)	Nu	Nu	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	Rigel Pharmaceuticals, Inc.	internaţional	A Phase 3 Open Label Extension Study of Fostamatinib Disodium in the Treatment of Persistent/Chronic Immune Thrombocytopenic Purpura	III	6		**20.10.2015**		**14.04.2016**	**16.06.2016**	
236	**M14-197, Amendment 1, dated 16.02.2015 VHP2014143**	2014-003558-15	ABT-122	Adalimumab®	Da	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 2 Study to Investigate the Safety, Tolerability and Efficacy of ABT-122 in Subjects with Active Psoriatic Arthritis Who Have an Inadequate Response to Methotrexate	II	24		**09.04.2015**		**26.10.2015**	**01.07.2016**	
237	**ZS-005, Amendment 2A, dated 10.03.2015 VHP2014139**	2014-004555-31	ZS (sodium zirconium cyclosilicate)	Nu	Da	Fenomene fiziologice celulare	CTG Cardiomed CRO Cristina Oana Micsescu E-mail:cristina.micsescu@ctgcro.com	ZS Pharma Inc.	internaţional	A Phase 3 Multicenter, Multi-dose, Open-label Maintenance Study to Investigate the Long-term Safety and Efficacy of ZS (Sodium Zirconium Cyclosilicate), an Oral Sorbent, in Subjects with Hyperkalemia, including a Randomized, Double-blind, Placebo controlled, Withdrawal Study	III	10		**15.04.2015**	**16.04.2015**		**25.11.2015**	
238	**CL2-78989-011, version Final, dated 04.03.2015 VHP2014133**	2013-003610-41	gevokizumab (S78989)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Servier Pharma SRL Elena Ionescu-Amza E-mail: elena.ionescu-amza@ro.netgrs.com	Institut de Recherches Internationales Servier	internaţional	Dose-response study of gevokizumab (S78989) 3mg, 10mg, 30mg or 60mg in patients with type 2 diabetes and diabetic kidney disease (DKD). A 66-week, international, multicenter, randomized, double-blind, parallel-group, placebo controlled study	II	50		**10.06.2015**		**17.08.2015**	**22.09.2015**	
239	**SP0982, Amendment 3, dated 09.01.2015**	2011-003100-21	Vimpat® (lacosamide, SPM927)	Nu	Da	Afecţiuni ale sistemului nervos	Pharmaceutical Research Associates Romania SRL Ruxandra Popescu E-mail: popescuruxandra@prahs.com	UCB Biosciences, Inc.	internaţional	A double-blind, randomized, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy and safety of Lacosamide as adjunctive therapy for uncontrolled primary generalized tonic-clonic seizures in subjects with idiopathic generalized epilepsy	III	6		**01.10.2015**	**08.10.2015**	**19.05.2016**		
240	**EP0012, Amendment 1, dated 27.01.2015**	2012-001770-29	Vimpat® (lacosamide, SPM927)	Nu	Nu	Afecţiuni ale sistemului nervos	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail: comesioana@prahs.com	UCB Biosciences, Inc.	internaţional	An open-label, multicenter extension study to evaluate the long-term safety and efficacy of Lacosamide as adjunctive therapy for uncontrolled primary generalized tonic-clonic seizures in subjects with idiopathic generalized epilepsy	III	6		**01.10.2015**	**08.10.2015**	**14.11.2016**		
241	**ALX0061-C203, version 2.0, dated 17.02.2015**	2014-003034-42	ALX-0061	Nu	Nu	Afecţiuni ale sistemului imunitar	Worldwide Clinical Trials Ltd Laura Mirela Neagu E-mail: laura.neagu@wwctrials.com	Ablynx NV	internaţional	A Phase II Multicenter, Open-Label Extension Study Assessing the Long-Term Efficacy and Safety of Subcutaneous ALX-0061 in Subjects with Moderate to Severe Rheumatoid Arthritis who Have Completed One of the Preceding Phase IIb Studies with ALX-0061	II	23		**16.10.2015**					
242	**CA209-171, Revised Protocol 02, dated 26.02.2015 VHP2015002**	2014-001285-10	nivolumab (BMS-936558)	Nu	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	An Open-Label, Multicenter Clinical Trial with Nivolumab (BMS-936558) Monotherapy in Subjects with Advanced or Metastatic Squamous Cell (Sq) Non-Small Cell Lung Cancer (NSCLC) who Have Received at Least One Prior Systemic Regimens for the Treatment of Stage IIIb/IV SqNSCLC	II	48		**27.07.2015**	**29.06.2015**	**03.08.2015**		
243	**ACT14205, version 1, dated 24.12.2014**	2014-005696-93	SAR125844	Nu	Nu	Afecţiuni oncologice	sanofi-aventis Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	Sanofi-aventis recherche & développement	internaţional	Phase II, Open Label, Single Arm Study Assessing the Clinical Benefit of SAR125844, Administered as Single Agent by Weekly Intravenous (IV) Infusion, for the Treatment of Patients with Advanced Pretreated Non-Small Cell Lung Cancer (NSCLC) Harboring MET Gene Amplification	II	5		**17.08.2015**			**05.01.2016**	
244	**PTK0796-ABSI-1108, version 1.0, dated 13.02.2015**	2013-003644-23	omadacycline (PTK 0796, neopentyl aminomethylminocycline)	Zyvox® (linezolid)	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Paratek Pharma LLC	internaţional	A Phase 3 Randomized, Double-Blind, Multi-Center Study to Compare the Safety and Efficacy of Omadacycline IV/PO to Linezolid IV/PO for Treating Adult Subjects with Acute Bacterial Skin and Skin Structure Infection (ABSSSI)	III	49		**24.08.2015**		**04.12.2015**	**03.05.2016**	
245	**PM1183-C-004-14, version 1.0, dated 04.12.2014**	2014-005251-39	lurbinectedin (PM01183)	Caelyx® (pegylated liposomal doxorubicin hydrochloride) Hycamtin® (topotecan hydrochloride)	Nu	Afecţiuni oncologice	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	Pharma Mar S.A	internaţional	Phase III Randomized Clinical Trial of Lurbinectedin (PM01183) versus Pegylated Liposomal Doxorubicin or Topotecan in Patients with Platinum-resistant Ovarian Cancer (CORAIL Trial)	III	28		**27.08.2015**		**02.11.2015**		
246	**SP0967, Amendment 1, dated 14.01.2015**	2013-000717-20	Vimpat® (lacosamide, SPM927)	Nu	Da	Afecţiuni ale sistemului nervos	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail: comesioana@prahs.com	UCB Biosciences Inc.	internaţional	A Multicenter, Double blind, Randomized, Placebo controlled, Parallel-group Study to Investigate the Efficacy and Safety of Lacosamide as Adjunctive Therapy in Subjects with epilepsy ≥1 Month to <4 Years of Age with Partial-Onset Seizures	III	2		**16.11.2015**	**30.07.2015**	**11.08.2016**		
247	**PTK0796-CABP-1200, version 1.0, dated 13.02.2015**	2013-004071-13	omadacycline (PTK 0796, neopentyl aminomethylminocycline)	Avelox® (moxifloxacin)	Da	Afecţiuni ale tractului respirator	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Paratek Pharma LLC	internaţional	A Phase 3 Randomized, Double-Blind, Multi-Center Study to Compare the Safety and Efficacy of Omadacycline IV/PO to Moxifloxacin IV/PO for Treating Adult Subjects with Community-Acquired Bacterial Pneumonia (CABP)	III	81		**17.09.2015**		**01.04.2016**	**17.02.2017**	

248	**XM22-ONC-40041, Amendment 1, dated 03.03.2015 VHP2015006**	2014-005096-85	Lonquex® (lipegfilgrastim, XM22)	Neulasta® (pegfilgrastim)	Da	Afecţiuni oncologice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Merckle GmbH	internaţional	Safety and Efficacy of LONQUEX® (Lipegfilgrastim) in Comparison to Pegfilgrastim (Neulasta®, Amgen Inc.) and Placebo in Patients with Non-Small-Cell Lung Cancer Receiving First-Line Chemotherapy	IV	28		**08.05.2015**		**09.12.2015**		
249	**Aramchol 005 (ARREST), (Amended #3, dated 17.01.2015 initial) Local Amended protocol (Romania) #3.1, dated 07.10.2015**	2014-003107-29	aramchol (arachidyl amido cholanoic acid)	Nu	Da	Afecţiuni nutriţionale şi metabolice	GCOP SRL Celia Soare E-mail: celia.soare@gconet.ro	Galmed Pharmaceuticals Ltd.	internaţional	A Phase IIb, double blind, randomized controlled clinical trial to evaluate the efficacy and safety of two Aramchol doses versus placebo in patients with Non-Alcoholic-Steatohepatitis (NASH)	II	10		**20.10.2015**	**23.07.2015**	**03.12.2015**		
250	**SGI-110-04, version 2.0, dated 06.03.2015 VHP2014141**	2014-001233-89	SGI-110	cytarabine decitabine azacitidine	Nu	Afecţiuni oncologice	Gregory Fryer Associates Ltd (GFA) Mike Bateman E-mail: mbateman@gf-associates.co.uk	Astex Pharmaceuticals, Inc.	internaţional	A Phase 3, Multicenter, Open-label, Randomized Study of SGI-110 versus Treatment Choice (TC) in Adults with Previously Untreated Acute Myeloid Leukemia (AML) Who Are Not Considered Candidates for Intensive Remission Induction Chemotherapy	III	450		**10.06.2015**		**05.10.2015**		
251	**C25006, Amendment 1, dated 15.03.2013**	2012-004128-39	Adcetris® (brentuximab vedotin, SGN-35)	Nu	Nu	Afecţiuni oncologice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-.eugen.almasan@quintiles.com	Millennium Pharmaceuticals, Inc.	internaţional	A Phase 4, Open-label, Single-Arm Study of Brentuximab Vedotin in Patients With Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma	IV	4		**02.11.2015**		**14.04.2016**		
252	**GS-US-279-1503, Amendment 1.2, dated 17.03.2015 VHP2014145**	2014-003994-41	GS-6615	Nu	Da	Afecţiuni cardiovasculare	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppdi.com	Gilead Sciences, Inc.	internaţional	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Study of GS-6615 in Subjects with Chronic Stable Angina and Coronary Artery Disease	II	20		**04.05.2015**			**26.05.2015**	
253	**XM22-08, (dated 02.02.2015 initial), Amendment 01, dated 13.05.2015**	2015-000087-34	Lonquex® (lipegfilgrastim, XM22)	Neupogen® (filgrastim)	Nu	Afecţiuni limfatice şi ale sângelui	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Merckle GmbH	internaţional	An Open-Label, Randomized, Active-Controlled, Multicenter Study to Evaluate the Efficacy, Pharmacokinetics, Pharmacodynamics, Safety, Tolerability, and Immunogenicity of Lipegfilgrastim 100 µg/kg Body Weight in Comparison to Filgrastim 5 µg/kg Body Weight in Pediatric Patients Diagnosed with Ewing Family of Tumors or Rhabdomyosarcoma Receiving Chemotherapy	II	8		**24.09.2015**	**06.07.2015**		**07.01.2016**	
254	**3098012, version 1.0, dated 19.12.2014**	2014-000217-30	ORM-12741	Nu	Da	Afecţiuni ale sistemului nervos	Worldwide Clinical Trials Ltd Sophie Humphrey E-mai: sophie humphrey@wwctrials.com	Orion Corporation	internaţional	Efficacy OF ORM-12741 On Agitation/Aggression Symptoms in Patients with Alzheimer's Disease: A Randomised, Double-Blind, Placebo-controlled, Parallel Group, Multicentre Study of 12 Weeks	II	70		**17.11.2015**	**28.07.2015**	**28.12.2015**		
255	**M14-198, dated 08.12.2014 VHP2015025**	2014-005527-27	ABT-122	Nu	Nu	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: Doina.Dobjanschi@INCResearch.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 2, Multicenter, Open-Label Extension (OLE) Study with ABT-122 in Active Psoriatic Arthritis Subjects Who Have Completed a Preceding Study M14-197 Phase 2 Randomized Controlled Trial (RCT)	II	16		**04.05.2015**		**15.02.2016**	**27.06.2016**	
256	**CH-ACM-01-FU, version 1.0, dated 11.03.2015**	2015-001292-51	octreotin (octreotide)	Nu	Nu	Afecţiuni hormonale	Accelsiors S.R.L. Monica Velculescu E-mail: m.velculescu@accelsiors.com	Chiasma, Inc.	internaţional	Follow-Up Study in Patients with Acromegaly Previously Participating in Chiasma Study CH-ACM-01	III	9		**06.08.2015**		**12.08.2015**	**08.01.2016**	
257	**I1F-MC-RHBP, dated 03.04.2015**	2015-000190-12	Ixekizumab (LY2439821)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	Eli Lilly Romania Luminita Butnaru E-mail: butnaru_luminita@lilly.com	Eli Lilly and Company	internaţional	A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Ixekizumab Dosing Regimens in Patients with Moderate-to-Severe Plaque Psoriasis	III	24		**14.08.2015**	**30.07.2015**	**16.09.2015**		
258	**TV1106-IMM-30021, dated 05.01.2015**	2014-003796-32	albutropin (TV-1106)	Nu	Da	Afecţiuni hormonale	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Teva Pharmaceutical Industries Ltd.	internaţional	A phase 3, multicenter, randomized, double-blind, placebo-controlled efficacy, safety and tolerability study of TV-1106 in growth hormone-deficient adults who are not current users of rhGH treatment	III	30		**18.11.2015**	**16.09.2015**		**18.12.2015**	
259	**GO29431, version 02, dated 24.04.2015 VHP2015020**	2014-003083-21	MPDL3280A (RO5541267)	Nu	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Elveţia	internaţional	A Phase III, Open-Label, Randomized Study of Atezolizumab (Anti−PD-L1 Antibody) Compared With A Platinum Agent (Cisplatin or Carboplatin) in Combination with Either Pemetrexed or Gemcitabine For PD-L1−Selected, Chemotherapy-Naive Patients with Stage IV Non-Squamous or Squamous Non−Small Cell Lung Cancer	III	35		**12.06.2015**		**29.10.2015**		
260	**GO29432, version 02, dated 24.04.2015 VHP2015021**	2014-003106-33	MPDL3280A (RO5541267)	Nu	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Elveţia	internaţional	A phase III, Open-Label, Randomized Study of Atezolizumab (ANTI-PD L1 Antibody) Compared with Gemcitabine+Cisplatin or Carboplatin for PD L1-Selected, Chemotherapy Naïve Patients with Stage IV Squamous Non-Small Cell Lung Cancer	III	25		**12.06.2015**		**11.12.2015**		

261	**I3Y-MC-JPBX, dated 27.03.2015**	2014-004832-20	abemaciclib (LY2835219)	docetaxel	Nu	Afecţiuni oncologice	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company	internaţional	A Randomized Phase 2 Study of Abemaciclib (LY2835219) versus Docetaxel in Patients with Stage IV Squamous Non-Small Cell Lung Cancer Previously Treated with Platinum-based Chemotherapy	II	12		**17.09.2015**	**23.07.2015**	**03.11.2015**		
262	**CNVA237A2320, version 01, dated 10.12.2014 VHP2015024**	2014-004818-28	Seebri Breezhaler® (glycopyrronium bromide, NVA237)	glycopyrronium bromide	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Irina Simion E-mail: irina.simion@parexel.com	Novartis Pharma Services AG	internaţional	A randomized, double-blind, parallel group, 26-week study evaluating the efficacy, safety and tolerability of NVA237 given once or twice daily, in patients with moderate and severe chronic obstructive pulmonary disease	IV	110		**08.07.2015**	**27.07.2015**	**14.10.2015**	**16.11.2016**	
263	**GS-US-313-0124, version 6.0, dated 31.10.2014 VHP201305**	2012-004013-13	Zydelig® (idelalisib, GS-1101)	Mabthera® (rituximab)	Da	Afecţiuni oncologice	Pharmaceutical Research Associates Romania SRL Oana David E-mail: davidoana@prahs.com	Gilead Sciences, Inc.	internaţional	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy and Safety of Idelalisib (GS-1101) in Combination with Rituximab for Previously Treated Indolent Non-Hodgkin Lymphomas	III	20		**10.06.2015**		**28.10.2015**	**07.03.2016**	
264	**009175QM, version 1, dated 26.01.2015**	2013-002403-34	AZD2014 everolimus fulvestrant	Nu	Nu	Afecţiuni oncologice	Comac Medical SRL Raluca Damian E-mail: raluca.damian@comac-medical.com	Queen Mary, University of London	internaţional	A Randomized Phase II Study of Fulvestrant in Combination with the dual mTOR Inhibitor AZD2014 or Everolimus or Fulvestrant alone in Estrogen Receptor-Positive Advanced or Metastatic Breast Cancer	II	34		**07.12.2015**		**15.03.2016**		
265	**42756493BLC2001, Amendment 1, dated 02.04.2015**	2014-002408-26	JNJ-42756493 (R601230)	Nu	Nu	Afecţiuni oncologice	Johnson & Johnson Romania S.R.L. Matei Alexandru Nica E-mail: mnica@its.jnj.com	Janssen-Cilag International NV	internaţional	A Phase 2, 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	II	18		**23.11.2015**	**03.11.2015**	**03.05.2016**		
266	**D3461C00005, version 2.0, dated 09.04.2015**	2014-004633-96	anifrolumab	Nu	Da	Afecţiuni ale sistemului imunitar	Pharmaceutical Research Associates Romania SRL Oana Gabriela-Nadia David E-mail: davidoana@prahs.com	AstraZeneca AB	internaţional	A Multicentre, Randomised, Double-blind, Placebo-controlled, Phase 3 Study Evaluating the Efficacy and Safety of Two Doses of Anifrolumab in Adult Subjects with Active Systemic Lupus Erythematosus	III	18		**18.11.2015**	**26.11.2015**	**24.02.2016**		
267	**FKB327-003, version 3.0, dated 23.03.2015 VHP2015013**	2014-000110-61	adalimumab (FKB327)	Humira® (adalimumab)	Nu	Afecţiuni ale sistemului imunitar	Cebis International SRL Mihai Manolache E-mail: bmihai.manolache@cebis-int.com	Fujifilm Kyowa Kirin Biologics Co., Ltd.	internaţional	An Open-label Extension Study to Compare the Long-term Efficacy, Safety, Immunogenicity and Pharmacokinetics of FKB327 and Humira® in Patients with Rheumatoid Arthritis on Concomitant Methotrexate	III	54		**27.08.2015**		**14.12.2015**		
268	**CV181-365, (version 01, dated 11.03.2015 initial), version 02, (Incorporates Amendment 03), dated 12.08.2015**	2014-003721-18	Onglyza® (saxagliptin) Forxiga® (dapagliflozin)	Glimepiride® (glimepiride)	Da	Afecţiuni nutriţionale şi metabolice	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	AstraZeneca AB, Sweden	internaţional	A 52-week International, Multicenter, Randomized, Double-Blind, Active-Controlled, Parallel Group, Phase 3bTrial with a Blinded 104-week Long -term Extension Period to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin in combination with Metformin Compared to Glimepiride in Combination with Metformin in Adult Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Therapy Alone	III	45		**07.12.2015**	**12.10.2015**	**06.01.2016**		
269	**CAIN457A3302, (version 00, dated 09.01.2015 initial), version 01, dated 16.06.2015**	2014-005339-15	Cosentyx® (secukinumab, AIN457)	Nu	Nu	Afecţiuni ale pielii şi ţesutului conjunctiv	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	Long term clear skin maintenance treatment optimization in patients with moderate to severe chronic plaque psoriasis: A randomized, multicenter, open-label with blinded-assessment, comparative, 52 week study to evaluate the efficacy, safety and tolerability of secukinumab 300 mg s.c.	III	80		**22.01.2016**				
270	**G200901, version 2.0, dated 22.04.2015**	2014-004989-23	enobosarm (GTx-024)	Nu	Nu	Afecţiuni oncologice	Cmed Group Limited Geoff Fatzinger E-mail: ovittos@cmedresearch.com	GTx, Inc.	internaţional	A Phase 2 Open Label, Multi-Center, Multinational Study Investigating The Efficacy and Safety Of GTx-024 On Advanced, Androgen Receptor-Positive Triple Negative Breast Cancer (AR+ TNBC)	II	20		**24.02.2016**	**28.09.2015**	**08.07.2016**	**22.11.2016**	
271	**MEIN14/FEB-PWV/001, version 1.3, dated 10.04.2015 VHP2015028**	2014-005567-33	Adenuric® (febuxostat)	Allopurinol® (allopurinol)	Nu	Afecţiuni nutriţionale şi metabolice	Ergomed GmbH Claudia Möschl E-mail: claudia.moeschl@ergomedplc.com	Menarini International Operations Luxembourg S.A	internaţional	The Effect of Intensive Urate Lowering Therapy (ULT) with Febuxostat in Comparison with Allopurinol on Cardiovascular Risk in Patients with Gout Using Surrogate Markers: a Randomized, Controlled Trial (Acronym: the FORWARD Trial)	IV	30		**17.06.2015**		**15.10.2016**	**10.05.2017**	
272	**MTC8-2014-1, version 3.0, dated 11.11.2014**	2014-000178-20	Teatrois® (tiratricol)	Nu	Nu	Afecţiuni hormonale	Spitalul Clinic de Psihiatrie "Prof. Dr. Alexandru Obregia" Bucureşti Dana Cristina Craiu E-mail: dcraiu@yahoo.com	Erasmus Medical Centre	internaţional	Thyroid hormone analong therapy pf patients with severe psychomotor retardation caused by mutations in the MCT8 thyroid hormone transporter: the Triac Trial	II	2		**15.07.2015**				
273	**B7391003, Amendment 1, dated 05.05.2015 VHP2015026**	2014-003878-16	bevacizumab (PF-06439535)	Avastin® (bevacizumab)	Nu	Afecţiuni oncologice	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Pfizer Inc.	internaţional	A Phase 3 randomized, double-blind study of PF-06439535 plus Paclitaxel-Carboplatin and Bevacizumab plus Paclitaxel-Carboplatin for the first-line treatment of patients with advanced non-squamous non-small cell lung cancer	III	46		**15.07.2015**	**27.05.2015**	**06.08.2015**		**01.03.2016**

274	**42160443PAI3003, Amen INT-3, dated 09.02.2015**	2014-002598-13	fulranumab (JNJ-42160443)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	InVentiv Health Clinical Romania S.R.L. Mădălina Variu E-mail: madalina.variu@inventivhealth.com	Janssen-Cilag International N.V.	internaţional	Randomized, 16-Week, Multi-Phase, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of Fulranumab as Monotherapy in Subjects with Signs and Symptoms of Osteoarthritis of the Hip or Knee	III	24		**07.01.2016**			**01.04.2016**	
275	**42160443PAI3007, Am INT-3, dated 09.02.2015**	2014-003224-40	fulranumab (JNJ-42160443)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	InVentiv Health Clinical Romania S.R.L. Mădălina Variu E-mail: madalina.variu@inventivhealth.com	Janssen-Cilag International N.V.	internaţional	Randomized, 16-Week, Multi-Phase, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, and Efficacy of Fulranumab as Adjunctive Therapy in Subjects with Signs and Symptoms of Osteoarthritis of the Hip or Knee	III	24		**07.01.2016**			**01.04.2016**	
276	**CNTO1275UCO3001, (dated 17.03.2015 initial), version Amendment 1, dated 14.07.2015**	2014-005606-38	ustekinumab (CNTO1275) Stelara® (ustekinumab, CNTO1275)	Nu	Da	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Sinziana Oana E-mail: sinziana.oana@parexel.com	Janssen-Cilag International NV	internaţional	A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of Ustekinumab Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis	III	24		**21.12.2015**				
277	**AS0005, version Final, dated 27.03.2015**	2015-000339-34	Cimzia® (certolizumab pegol, CDP870)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	PAREXEL International Romania s.r.l. Amelia Cristina Caciula E-mail: amelia.caciula@parexel.com	UCB BIOSCIENCES GmbH	internaţional	Multicenter, open-label (Part A) followed by a randomized, double-blind, parallel-group, placebo-controlled study (Part B) to evaluate maintenance of remission in subjects with active axial spondyloarthritis (AXSPA) receiving either Certolizumab pegol 200mg Q2W or 200mg Q4W as compared to placebo	III	30		**28.01.2016**		**03.03.2016**		
278	**CFOR258D2416, version 01, dated 22.04.2015 VHP2015017**	2012-004854-27	Foradil® (formoterol fumarate, FOR258)	Flutide Diskus® (fluticasone propionate)	Da	Afecţiuni ale tractului respirator	Novartis Pharma Services Romania S.R.L. Alexandru Ionel E-mail: alexandru.ionel@novartis.com	Novartis Pharma services AG	internaţional	A 26 week, randomized, active-controlled safety study of double-blind formoterol fumarate in free combination with an inhaled corticosteroid versus an inhaled corticosteroid in adolescent and adult patients with persistent asthma	III	312		**25.08.2015**			**15.10.2015**	
279	**15-17, version Final 1.0, dated 07.0**	2015-001747-37	Aloxi® (palonosetron)	Aloxi® (palonosetron)	Da	Afecţiuni oncologice	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Helsinn Healthcare SA	internaţional	A phase 3, single-dose, multicenter, randomized, double-blind, parallel group study to assess the efficacy and safety of palonosetron 0.25 mg administered as a 30-minute IV infusion compared to palonosetron 0.25 mg administered as a 30-second IV bolus for the prevention of chemotherapy-induced nausea and vomiting in cancer patients receiving highly emetogenic chemotherapy	III	57		**22.10.2015**		**09.11.2015**	**09.03.2016**	
280	**6603/1132, (version 2.0, dated 15.04.2015 initial), version 3.0, dated 09.09.2015**	2014-001449-26	condoliase (SI-6603)	Nu	Nu	Afecţiuni ale sistemului musculo-scheletic	PAREXEL International Romania s.r.l. Mirela Bogdan E-mail: Mirela.Bogdan@parexel.com	Seikagaku Corporation	internaţional	A Multicenter, Open-label Study of SI-6603 in Patients with Lumbar Disc Herniation (Phase III)	III	90		**18.01.2016**	**24.11.2015**	**13.04.2016**	**17.03.2017**	
281	**LX4211.1-310-T1DM, version AMD 2, dated 15.05.2015**	2014-005153-39	LX4211	Nu	Da	Afecţiuni nutriţionale şi metabolice	Covance Clinical and Periapproval Services Limited Andreea Curcă E-mail: andreea.curca@covance.com	Lexicon Pharmaceuticals, Inc.	internaţional	A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of LX4211 as Adjunct Therapy in Adult Patients with Type 1 Diabetes Mellitus Who Have Inadequate Glycemic Control with Insulin Therapy	III	70		**10.11.2015**	**24.09.2015**	**26.11.2015**		
282	**EMR100070-004, version 2.0, dated 05.05.2015 VHP2015037**	2014-005060-15	avelumab (MSB0010718C)	Docetaxel Hospira® (docetaxel)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Merck KGaA	internaţional	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	III	11		**17.06.2015**		**17.11.2015**		
283	**NN7999-3895, version 2.0, dated 25.03.2015 VHP2015042**	2012-004867-38	N9-GP (nonacog beta pegol)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Novo Nordisk Farma SRL Cătălin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S	internaţional	Safety and Efficacy of nonacog beta pegol (N9-GP) in Previously Untreated Patients with Haemophilia B An open-label single-arm multicentre non-controlled phase 3a trial investigating safety and efficacy of nonacog beta pegol (N9-GP) in prophylaxis and treatment of bleeding episodes in previously untreated patients with haemophilia B (FIX activity ≤2%)	III	1		**03.07.2015**			**14.03.2016**	
284	**MK-3475-062, version 00, dated 05.05.2015**	2015-000972-88	pembrolizumab (MK3475)	Fluorouracil-GRY® (fluorouracil) Cisplatin Teva® (cisplatin)	Da	Afecţiuni oncologice	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co.	internaţional	A Randomized, Active-Controlled, Partially Blinded, Biomarker Select, Phase III Clinical Trial of Pembrolizumab as Monotherapy and in Combination with Cisplatin+5-Fluorouracil versus Placebo+Cisplatin+5-Fluorouracil as First-Line Treatment in Subjects with Advanced Gastric or Gastroesophageal Junction (GEJ) Adenocarcinoma	III	20		**18.02.2016**	**28.01.2016**		**28.03.2017**	**02.03.2016**
285	**GQM05, version 5.0, dated 18.03.2015**	2013-001231-51	influenza vaccine (481)	Vaxigrip®	Da	Afecţiuni virale	Sanofi Romania SRL Alexandra Voicu Teodora Teodoreanu E-mail: Teodora.Teodoreanu@sanofi.com	Sanofi Pasteur	internaţional	Efficacy and Immunogenicity Study of Quadrivalent Influenza Vaccine Administered via the Intramuscular Route in Healthy Children Aged 6 to 35 Months	III	142		**30.10.2015**	**29.10.2015**	**10.11.2015**	**27.07.2016**	
286	**1302.5, version 2.0, dated 01.04.2015**	2014-002161-30	BI 695502	Avastin® (bevacizumab)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Andrei Cojocaru E-mail: andrei.cojocaru@quintiles.com	Boehringer Ingelheim International GmbH	internaţional	A multicenter, randomized, double-blind Phase III trial to evaluate efficacy and safety of BI 695502 plus chemotherapy versus Avastin® plus chemotherapy in patients with advanced nonsquamous Non-Small Cell Lung Cancer	III	17		**14.03.2016**		**13.07.2016**		

287	**CT-P10 3.4, (version 1.2. dated 20.03.2015 initial), version 2.4, dated 16.03.2016**	2014-005324-10	CT-P10 (rituximab)	Rituxan® (rituximab)	Nu	Afecţiuni oncologice	PPD Romania SRL Elena Calina E-mail: elena.calina@ppdi.com	Celltrion, Inc.	internaţional	A Phase 3, Randomised, Parallel-Group, Active-Controlled, Double-Blind Study to Compare Efficacy and Safety between CT-P10 and Rituxan in Patients with Low Tumour Burden Follicular Lymphoma	III	10		**24.03.2016**				
288	**CRFB002H2301, (version 00, dated 14.11.2014 initial), version 01, dated 05.08.2015**	2014-003041-10	Lucentis® (ranibizumab, RFB002)	Nu	Nu	Afecţiuni oculare	PAREXEL International Romania SRL Andreea Raluca Ghinea E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	RAINBOW study: a randomized, controlled study evaluating the efficacy and safety of RAnibizumab compared with laser therapy for the treatment of INfants BOrn prematurely With retinopathy of prematurity	III	300		**19.04.2016**		**21.09.2016**		
289	**GS-EU-174-1403, amendment 2, dated 10.03.2015**	2014-004939-39	Viread® (tenofovir disoproxil fumarate)	Nu	Nu	Afecţiuni virale	Pharmaceutical Research Associates Romania SRL Oana David E-mail: davidoana@prahs.com	Gilead Sciences International Ltd.	internaţional	Pharmacoepidemiology study to define the long-term safety profile of tenofovir disoproxil fumarate (Tenofovir DF, Viread®) and describe the management of Tenofovir DF-associated renal and bone toxicity in Chronic Hepatitis B (CHB)-infected adolescents aged 12 to <18 years in Europe	IV	24		**17.02.2016**		**07.06.2016**		
290	**009246QM, version 2, dated 11.02.2014**	2013-001521-43	AZD5363	Nu	Da	Afecţiuni oncologice	Comac Medical SRL Rodica Avram E-mail: rodica.avram@comac-medical.com	Queen Mary, University of London	internaţional	A Phase II, double blind, randomised, placebo-controlled study of the AKT inhibitor AZD5363 in combination with paclitaxel in triple-negative advanced or metastatic breast cancer	II	22		**07.12.2015**		**12.08.2016**		
291	**MK-0517-044, version 00, dated 07.05.2015**	2014-001783-34	fosaprepitant dimeglumine (MK-0517)	ondansetron	Da	Afecţiuni oncologice	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A phase III, randomized, placebo-controlled clinical trial to study the efficacy and safety of MK-517/fosaprepitant and ondansetron versus ondansetron for the prevention of chemotherapy-induced nausea and vomiting (CINV) in pediatric subjects receiving emetogenic chemotherapy	III	18		**27.06.2016**			**05.08.2016**	
292	**A5481044, Amendment1, dated 09.04.2015**	2015-000515-41	palbociclib (PD-0332991) Erbitux® (cetuximab)	Erbitux® (cetuximab)	Da	Afecţiuni oncologice	inVentiv Health Clinical Romania S.R.L. Irina Copaci E-mail: regopseurope@inventivhealth.com	Pfizer Inc.	internaţional	A randomized, multicenter, double-blind phase 2 study of palbociclib plus cetuximab versus cetuximab for the treatment of human Papillomavirus-negative, cetuximab-naïve patients with recurrent/metastatic squamous cell carcinoma of the head and neck after failure of one prior Platinum-containing Chemotherapy Regimen	II	9		**11.03.2016**			**25.05.2016**	
293	**CSL689_2001, Amendment 1, dated 04.02.2015**	2012-001309-26	CSL689 (recombinant fusion protein, linking activated coagulation factor VII with albumin, rVIIa-FP)	NovoSeven® (eptacog alfa)	Nu	Afecţiuni limfatice şi ale sângelui	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	CSL Behring GmbH	internaţional	A multicenter, open-label, multiple-dose, dose escalation study to investigate the pharmacokinetics, efficacy, and safety of rVIIa-FP (CSL689) in subjects with hemophilia (A or B) and inhibitors	II/III	10		**03.03.2016**				
294	**CB-03-01/26, version 1.0, dated 11.06.2015**	2015-002623-26	cortexolone 17alpha-propionate (CB-03-01)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	InnoPharma International SRL Massmiliano Stasi E-mail: innopharma@innopharma.it persoana de contact Daniela Popescu Email: d.popescu@innopharma.it	CASSIOPEA SpA, Italy	internaţional	A Phase 3, Multicenter, Randomized, Double-Blind, Vehicle-Controlled Study to Evaluate the Safety and Efficacy of Cortexolone 17α-Propionate (CB-03-01) 1% Cream Applied Twice-Daily for 12 Weeks in Subjects with Facial Acne Vulgaris	III	176		**07.12.2015**	**23.12.2015**	**08.01.2016**		
295	**D5164C00001, version 1.0, dated 04.06.2015**	2015-000662-65	AZD9291	Nu	Da	Afecţiuni oncologice	AstraZeneca UK Ltd. Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB, Suedia	internaţional	A Phase III, double-blind, randomized, placebo-controlled multi-centre, study to assess the efficacy and safety of AZD9291 versus Placebo, in patients with Epidermal Growth Factor Receptor Mutation Positive stage IB-IIIA non-small cell lung carcinoma, following complete tumour resection with or without adjuvant chemotherapy (ADAURA)	III	25		**16.11.2015**		**13.01.2016**		
296	**VR475/3/001, version 1.0, 01.06.2015**	2015-000353-20	Budesonide nebuliser suspension delivered via the VR475 Inhalation System	Budesonide nebuliser suspension delivered by PARI BOY® Inhalation System	Da	Afecţiuni ale tractului respirator	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Vectura Limited	internaţional	A randomised, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of two doses of nebulised budesonide delivered by the VR475 Inhalation System, with an open-label comparison to conventionally nebulised budesonide, in patients with uncontrolled asthma despite treatment with high dose inhaled corticosteroid and at least a second controller (GINA Step 4) and those receiving oral corticosteroid (GINA Step 5)	III	64		**26.04.2016**	**21.12.2015**	**27.07.2016**		
297	**JNJ-DEP, (version 1.03, dated 05.05.2015 initial), version 1.04, dated 04.12.2015**	2015-002106-36	JNJ-39393406	Nu	Da	Afecţiuni ale sistemului nervos	Clinirx Tangent Research SRL Paul George Radu E-mail: paull.radu@clinirxtangent.com	Clinirx Tangent Research	naţional	The effects of JNJ-39393406 on psychometric performance and residual depressive symptoms in 80 patients with unipolar or bipolar depression: a phase II exploratory add-on double blind placebo controlled 2 week trial	II	80		**11.01.2016**	**09.11.2015**		**27.06.2016**	
298	**D4193C00002, Amendment 3.0, 01.06.2015 VHP2015046**	2014-003863-40	MEDI4736 tremelimumab (MEDI1123)	cetuximab docetaxel paclitaxel methotrexate 5-fluorouracil tegafur capecitabine	Nu	Afecţiuni oncologice	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail: comesioana@prahs.com	AstraZeneca AB	internaţional	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)	III	50		**05.08.2015**	**15.10.2015**	**19.02.2016**		**21.09.2016**
299	**GX-H9-003, version 1.0, dated 21.05.2015**	2015-001939-21	GX-H9 (hGH-hyFc, recombinant human growth hormone)	Genotropin® (somatropin)	Nu	Afecţiuni hormonale	Accelsiors S.R.L. Monica Velculescu E-mail: m.velculescu@accelsiors.com	Genexine, Inc.	internaţional	A phase 2, randomized, open-label, active controlled, dose finding study of the long-acting hybrid Fc fused recombinant human growth hormone (GX-H9) in paediatric patients with growth hormone deficiency	II	3		**26.04.2016**			**10.04.2017**	

300	**PEGF/USVIP3/003, version 1.0, dated 09.04.2015**	2015-000266-64	USV Pegfilgrastim (pegfilgrastim)	Neulasta® (pegfilgrastim)	Nu	Afecţiuni limfatice şi ale sângelui	Accelsiors S.R.L Monica Velculescu E-mail: m.velculescu@accelsiors.com	USV Private Limited	internaţional	A Randomised, Multi-Centre, Assessor-Blinded, Active-Controlled, Parallel Group, Equivalence Phase III Study Comparing the Safety and Efficacy of USV Pegfilgrastim and Neulasta® in Breast Cancer Patients Undergoing Myelosuppressive Chemotherapy	III	50		**22.01.2016**		**29.01.2016**	**06.02.2017**	
301	**DS5565-A-U307, (version 1.0, dated 30.03.2015 initial), version 2.0, dated 07.04.2016**	2014-003972-21	mirogabalin (DS-5565)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Daiichi Sankyo, Inc. United States	internaţional	A randomized, double-blind, placebo-controlled safety study of DS-5565 for treatment of pain due to Fibromyalgia in subjects with chronic kidney disease	III	3		**01.06.2016**		**28.10.2016**	**06.07.2017**	
302	**ESKETINTRD3004, (Amendment 1, dated 11.06.2015 initial), Amendment 4, 06.07.2016**	2014-004587-38	esketamine hydrochloride	Cymbalta® (duloxetine hydrochloride) Cipralex® (escitalopram) Zoloft® (sertraline hydrochloride) Trevilor® (venlafaxine hydrochloride)	Nu	Afecţiuni ale sistemului nervos	Johnson & Johnson Romania SRL Cosmin Gaghi E-mail: cgaghi@jnj.com	Janssen-Cilag International NV, Belgia	internaţional	An Open-label, Long-term, Safety and Efficacy Study of Intranasal Esketamine in Treatment-resistant Depression	III	56		**21.11.2016**	**25.02.2016**		**13.04.2017**	
303	**CBYL719C2301, version 00, dated 09.04.2015**	2015-000340-42	alpelisib (BYL719)	Faslodex® (fulvestrant)	Da	Afecţiuni oncologice	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	SOLAR-1: A phase III randomized double-blind, placebo controlled study of alpelisib in combination with fulvestrant for men and postmenopausal women with hormone receptor positive, HER2-negative advanced breast cancer which progressed on or after aromatase inhibitor treatment	III	18		**25.03.2016**	**03.03.2016**	**22.07.2016**		
304	**LP0076-1017, (version 4, dated 16.02.2015 initial), version 5.0, dated 14.08.2015**	2013-001538-16	Dovobet® (calcipotriol + betamethasone)	Nu	Nu	Afecţiuni ale pielii şi ţesutului conjunctiv	Premier Research Romania SRL Ana Popescu E-mail: ana.popescu@premier-research.com	LEO Pharma A/S	internaţional	Effect of Calcipotriol plus Betamethasone Dipropionate Gel on the HPA Axis and Calcium Metabolism in Adolescent Subjects (Aged 12 to 16 Years, 11 months) with Scalp and Body Psoriasis. A phase 2 trial evaluating the safety and efficacy of once daily use of LEO 80185 gel containing calcipotriol 50 mcg/g plus betamethasone 0.5 mg/g (as dipropionate) in adolescent subjects (aged 12 to 16 years, 11 months) with scalp and body psoriasis. An international, multi-centre, prospective, non-controlled, open, single-group, 8-week trial in adolescent subjects (aged 12 to 16 years, 11 months) with scalp and body psoriasis	II	15		**10.11.2015**	**26.10.2015**	**08.02.2016**		
305	**G200802, version 1.0, 26.05.2015**	2015-001012-35	enobosarm (GTx-024)	Nu	Nu	Afecţiuni oncologice	Cmed Clinical Research Services Ltd Geoff Fatzinger E-mail: ovittos@cmedresearch.com	GTx, Inc.	internaţional	A Phase 2 Open Label, Multi-Center, Multinational, Randomized, Parallel Design Study Investigating The Efficacy and Safety Of GTx-024 On Metastatic or Locally Advanced ER+/AR+ Breast Cancer (BC) in Postmenopausal Women	II	13		**24.02.2016**	**30.09.2015**	**14.05.2016**		
306	**FGCL-3019-067, Amendment 3.0, dated 28.05.2015**	2014-005658-20	FG-3019	Nu	Da	Afecţiuni ale tractului respirator	Quintiles Romania SRL Andrei Cojocaru E-mail: andrei.cojocaru@quintiles.com	FibroGen, Inc.	internaţional	A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of FG-3019 in Patients with Idiopathic Pulmonary Fibrosis	II	8		**06.06.2016**			**05.04.2016**	
307	**WO29479, version 03, dated 31.03.2015**	2014-002230-32	cobimetinib (GDC-0973, RO5514041/F0, GDC-0973/XL5184) Paclitaxel® (paclitaxel)	Nu	Da	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffman-La Roche Ltd.	internaţional	A Multistage, Phase II Study Evaluating the Safety and Efficacy of Cobimetinib Plus Paclitaxel, Cobimetinib Plus Atezolizumab Plus Paclitaxel, or Cobimetinib Plus Atezolizumab Plus Nab-Paclitaxel as First-Line Treatment for Patients With Metastatic Triple-Negative Breast Cancer	II	35		**11.03.2016**	**14.01.2016**	**01.04.2016**		
308	**EFC13691, version 2, dated 07.07.2015**	2015-001573-40	dupilumab (SAR231893)	Nu	Da	Afecţiuni ale tractului respirator	Sanofi Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	Sanofi-aventis recherche et développement	internaţional	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of Dupilumab in Patients with Severe Steroid Dependent Asthma	III	23		**09.02.2016**		**04.05.2016**		
309	**7655A-014, version 01, dated 09.06.2015**	2015-000246-34	imipenem+cilastatin+relebactam (MK-7655A)	Piperacillin/Tazobactam Teva® (piperacillin+tazobactam)	Nu	Infecţii bacteriene şi micoze	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Randomized, Double-Blind, Active Comparator-Controlled Clinical Trial to Study the Safety, Tolerability, and Efficacy of Imipenem/Cilastatin/Relebactam (MK-7655A) Versus Piperacillin/Tazobactam in Subjects with Hospital-Acquired Bacterial Pneumonia or Ventilator-Associated Bacterial Pneumonia	III	30		**08.01.2016**	**28.04.2016**	**11.10.2016**		
310	**C38072-AS-30025, Amendment 1, dated 04.05.2015**	2015-000865-29	reslizumab (CEP-38072)	Nu	Da	Afecţiuni ale tractului respirator	PPD Romania SRL Manuela Georgiana Botea E-mail: Manuela.Botea@ppd.com	Teva Branded Pharmaceutical Products R&D, Inc.	internaţional	A 52-Week Double-Blind, Placebo-Controlled, Parallel-Group Efficacy and Safety Study of Reslizumab 110 mg Fixed, Subcutaneous Dosing in Patients with Uncontrolled Asthma and Elevated Blood Eosinophils	III	14		**03.05.2016**	**26.11.2015**	**30.05.2016**		
311	**WA29767, version 3, dated 12.07.2015 VHP2015052**	2015-000424-28	RoActemra® (tocilizumab, RO487-7533/F10-04)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A phase III, multicenter, randomized, double blind, placebo-controlled, parallel-group study to assess the efficacy and safety of tocilizumab versus placebo in patients with systemic sclerosis	III	4		**25.08.2015**		**29.03.2016**		
312	**PI116678, version 02, dated 15.05.2015**	2014-001972-70	GSK2269557	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Roxana Gheorghiu roxana.d.gheorghiu@gsk.com	GlaxoSmithKline Research & Development	internaţional	A randomised, double-blind (sponsor unblinded), placebocontrolled, parallel-group, multicentre study to evaluate the efficacy and safety of GSK2269557 administered in addition to standard of care in adult subjects diagnosed with an acute exacerbation of Chronic Obstructive Pulmonary Disease	II	15		**07.12.2015**	**12.11.2015**	**06.01.2016**	**05.04.2016**	

313	**AB12009, version 6.0, dated 02.09.2014**	2012-005586-13	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni ale tractului respirator	HT Research RO SRL Nicoleta Carp E-mail:ncarp@hungarotrial.com	AB Science	internaţional	A prospective, multicentre, randomised, double-blind, placebo-controlled, phase 2a study to compare the efficacy and the safety of 24-week treatment with masitinib versus placebo in patients with severe Chronic Obstructive Pulmonary Disease (COPD)	II	12							
314	**UC-0160/1105 , version 6.0, dated 19.06.2015 (GETUG-AFU 21)**	2012-000142-35	Abiraterone Acetate® (abiraterone acetate)	Nu	Nu	Afecţiuni oncologice	UNICANCER R&D Romain Boidin E-mail: reglementaire@unicancer.fr	UNICANCER	internaţional	A prospective randomised phase III study of androgen deprivation therapy (+/- docetaxel) with or without local radiotherapy with or without abiraterone acetate and prednisone in patient with metastatic hormone-naïve prostate cancer	III	50		**13.01.2016**					
315	**AC-058B301, version 3, dated 16.07.2015 VHP2015053**	2012-000540-10	ponesimod (ACT-128800)	Aubagio® (teriflunomide)	Da	Afecţiuni ale sistemului nervos	Covance Clinical and Periapproval Services Limited Loredana Rădulescu E- mail:loredana@radulescu@covance.com	Actelion Pharmaceuticals Ltd	internaţional	Multicenter, randomized, double-blind, parallel-group, active-controlled, superiority study to compare the efficacy and safety of ponesimod to teriflunomide in subjects with relapsing multiple sclerosis	III	28		**28.09.2015**		**22.12.2015**			
316	**RPC01-3001, version 2.0, 16.07.2015**	2015-002500-91	ozanimod (RPC1063)	Nu	Nu	Afecţiuni ale sistemului nervos	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Celgene International II Sàrl (CIS II)	internaţional	A Multi-Site, Open-Label Extension Trial of Oral RPC1063 in Relapsing Multiple Sclerosis	III	48		**26.11.2015**		**27.01.2016**			
317	**BAY59-7939/17454, version 1.0, dated 23.03.2015**	2014-005569-58	Xarelto® (rivaroxaban)	Nu	Da	Afecţiuni cardiovasculare	Covance Clinical and Periapproval Services Limited Loredana Radulescu email:loredana.radulescu@covance.com	Bayer AG (BAG)	internaţional	An international, multicenter, randomized, double-blind, placebo-controlled phase 3 trial investigating the efficacy and safety of Rivaroxaban to reduce the risk of major thrombotic vascular events in patients with symptomatic peripheral artery disease undergoing lower extremity revascularization procedures	III	120		**21.12.2015**	**12.11.2015**	**25.02.2016**			
318	**56021927PCR3002, version Initial, dated 24.06.2015**	2015-000735-32	JNJ-56021927	Nu	Da	Afecţiuni oncologice	Johnson & Johnson Romania SRL Madalina Rotariu E-mail:mrotariu@its.jnj.com	Janssen-Cilag International NV	internaţional	A Phase 3 Randomized, Placebo-controlled, Double-blind Study of Apalutamide Plus Androgen Deprivation Therapy (ADT) Versus ADT in Subjects with Metastatic Hormone-sensitive Prostate Cancer (mHSPC)	III	50		**21.01.2016**	**18.01.2016**	**06.04.2016**			
319	**U31287-A-U203, (version 1.0, dated 25.06.2015 initial), version 2.0, dated 27.08.2015**	2015-002222-40	Patritumab (U3-1287) Carboplatin® (carboplatin) Erbitux® (cetuximab) Cisplatin® (cisplatin)	Nu	Da	Afecţiuni oncologice	Covance Clinical and Periapproval Services Limited Viorica Voicu E- mail:Viorica.Voicu@covance.com	Daiichi Sankyo, Inc. United States	internaţional	Randomized, Placebo-Controlled, Double Blind Phase 2 Study of Patritumab (U3-1287) in Combination with Cetuximab plus Platinum-Based Therapy in First Line Setting in Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	II	15		**09.05.2016**	**14.01.2016**				
320	**MLN0002-3026, version 02, dated 13.05.2015**	2015-000939-33	Entyvio® (vedolizumab IV, MLN0002) Humira® (adalimumab)	Nu	Da	Afecţiuni ale sistemului imunitar	Quintiles Romania S.R.L Andrei Cojocaru E-mail: andrei.cojocaru@quintiles.com	Takeda Development Centre Europe, Ltd.	internaţional	A Randomized, Double-Blind, Double-Dummy, Multicenter, Active- Controlled Study to Evaluate the Efficacy and Safety of Vedolizumab IV Compared to Adalimumab SC in Subjects With Ulcerative Colitis	III	18		**09.02.2016**		**17.05.2016**			
321	**CA209-227, (version Initial, dated 29.05.2015 initial), version Revised 01, dated 21.10.2015**	2014-003630-23	nivolumab (BMS-936558) ipilimumab (BMS-734016)	Paraplatin® (carboplatin) Cisplatin Neocorp® (cisplatin) Cisplatin Teva® (cisplatin) Gemcitabine® (gemcitabine hydrochloride) Alimta® (pemetrexed)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	An Open-Label, Randomized Phase 3 Trial of Nivolumab, or Nivolumab plus Ipilimumab, or Nivolumab plus platinum doublet chemotherapy versus platinum doublet chemotherapy in Subjects with Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)	III	60		**29.01.2016**	**23.11.2015**	**17.02.2016**			
322	**NN9535-4216, version 1.0, dated 14.07.2015**	2014-005375-91	semaglutide	Trulicity® (dulaglutide)	Nu	Afecţiuni nutriţionale şi metabolice	Novo Nordisk Farma SRL Cătălin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S	internaţional	Efficacy and safety of semaglutide versus dulaglutide as add-on to metformin in subjects with type 2 diabetes	III	60		**11.02.2016**		**23.02.2016**	**19.05.2017**		
323	**TZSA2, version 03, dated 22.07.2015**	2014-003040-12	Tizaspray® (tizanidine hydrochloride)	Sirdalud® (tizanidine hydrochloride)	Nu	Afecţiuni ale sistemului musculo-scheletic	LATIS SRL Enrico Serafini E-mail: serafini@latiscro.it	MDM S.p.A.	internaţional	A phase III, multicenter, randomized, parallel groups study to assess the efficacy and safety of 0.5 mg Tizaspray® administered intranasally versus Sirdalud® 2 mg tablets, in patients with acute low back pain	III	224		**23.02.2016**	**23.12.2015**	**15.03.2016**	**30.01.2017**		
324	**M13-590, version Original, dated 16.06.2015**	2015-002087-17	ABT-493/ABT-530	Nu	Nu	Afecţiuni virale	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 1 Infection (ENDURANCE-1)	III	35		**26.01.2016**			**06.01.2017**		
325	**1245.72, version 1.0, dated 14.07.2015**	2014-005256-26	empagliflozin (BI 10773) Jardiance® (empagliflozin)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Pharm-Olam International (UK) Ltd. Ramona Nicolescu E-mail: ramona.nicolescu@pharm-olam.com	Boehringer Ingelheim RCV GmbH & Co KG	internaţional	A Phase III, randomised, double blind, placebo-controlled, parallel group, efficacy, safety and tolerability trial of once daily, oral doses of empagliflozin as adjunctive to insulin therapy over 26 weeks in patients with Type 1 Diabetes Mellitus (EASE-3)	III	60		**28.03.2016**	**22.02.2016**	**15.05.2016**			

326	**ALGOSIN-1, (version 01, dated 28.08.2015 initial), versiunea 03, datată 22.12.2015**	2015-002314-74	Algopirin® (acetylsalicylic acid, acetaminophen, caffeine, chlorpheniramine maleate)	acetaminophen	Da	Afecţiuni ale sistemului musculo-scheletic	Universitatea de Medicina si Farmacie „Carol Davila" Ioanel Sinescu	Universitatea de Medicina si Farmacie „Carol Davila"	naţional	Studiu pe grupuri paralele, de non-inferioritate, randomizat, dublu orb, multidoza, pentru comparerea eficacitatii unei combinatii fixe de acid acetilsalicilic, acetaminofen, cofeina si clorfeniramin cu paracetamolul, in durerile lombare	IV	100		**04.04.2016**				
327	**CA209-331, version initial, dated 22.04.2015 VHP2015085**	2015-001097-18	nivolumab (BMS-936558)	Topotecan® (topotecan)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	An Open-label, Randomized, Phase 3 Study of Nivolumab or Chemotherapy in Subjects with Relapsed Small-cell Lung Cancer after Platinum-based First Line Chemotherapy	III	50		**30.10.2015**	**12.11.2015**	**25.11.2015**		
328	**RDD110, (version 1.5, dated 31.08.2015 initial), Version 1.6, dated 11 October, 2015 + Romania Local Amendment #2, dated 26 Jul 2016**	2014-003351-65	nifedipine	Nu	Da	Afecţiuni ale sistemului digestiv	CTG Cardiomed CRO Cristina Micsescu E-mail:cristina.micsescu@ctgcro.com	RDD Pharma Ltd.	internaţional	The Effect of Intra-anal Nifedipine, Used As Add-on to Conservative Therapy, on Pain in Patients with Anal Fissure	II/III	165		**24.08.2016**	**19.01.2016**	**03.11.2016**		
329	**NN1731-4214, version 1.0, dated 30.10.2014**	2015-001919-13	vatreptacog alfa	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Novo Nordisk Farma SRL Cătălin Buzarzan E-mail: catb@novonordisk.com	Novo Nordisk A/S	internaţional	Pharmacogenetic testing of saliva samples from patients with ≥5 exposure days to rFVIIa analogue in the adept™2 trial. Bio-specimen research study	II	2		**07.12.2015**	**17.03.2016**	**11.10.2016**		
330	**NAB-BC-3781-3101, (version 1.0, dated 01.07.2015 initial), version 2.0, dated 06.10.2015**	2014-005169-63	lefamulin (BC-3781)	Avelox® (moxifloxacin) Zyvox® (linezolid)	Da	Afecţiuni ale tractului respirator	PPD Romania SRL Brindusa Ilse Stoica brindusa.stoica@ppdi.com	Nabriva Therapeutics AG	internaţional	A Phase 3, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Lefamulin (BC 3781) Versus Moxifloxacin (With or Without Adjunctive Linezolid) in Adults With Community-Acquired Bacterial Pneumonia	III	60		**04.04.2016**		**13.07.2016**	**12.05.2017**	
331	**BIA-2093-311/EXT, version final 1.0, dated 02.06.2015**	2015-001243-36	eslicarbazepine acetate (BIA 2-093)	Nu	Nu	Afecţiuni ale sistemului nervos	Scope International SRL Tudor Mitu tmitu@scope-international.com	BIAL - Portela & Ca, S.A.	internaţional	Efficacy and safety of eslicarbazepine acetate (BIA 2-093) as monotherapy for patients with newly diagnosed partial-onset seizures: a double-blind, randomized, active-controlled, parallel-group, multicenter clinical study -open-label ESL extension	III	20		**22.02.2016**	**11.01.2016**	**27.03.2016**		
332	**MK-0431-838, version 00, dated 01.07.2015**	2014-005525-13	Januvia® (sitagliptin, MK-0431)	Forxiga® (dapagliflozin)	Da	Afecţiuni nutriţionale şi metabolice	Merck Sharp & Dohme Romania SRL Florina Prunduru E-mail: florina.prunduru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Multicenter, Randomized, Double-Blind, Active-Comparator Controlled Clinical Trial to Study the Safety and Efficacy of the Addition of Sitagliptin Compared with the Addition of Dapagliflozin in Subjects with Type 2 Diabetes Mellitus and Mild Renal Impairment Who Have Inadequate Glycemic Control on Metformin With or Without a Sulfonylurea	III	12		**24.02.2016**	**15.02.2016**	**05.04.2016**		
333	**YLB113-002, dated 29.07.2015**	2015-002809-12	YLB113 (etanercept)	Enbrel® (etanercept)	Nu	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	YL Biologics Ltd	internaţional	A comparative Study to Assess the Efficacy, Safety and Immunogenicity of YLB113 and Enbrel for the Treatment of Rheumatoid Arthritis	III	13		**05.05.2016**	**15.03.2016**	**30.05.2016**		
334	**LPS14245, version 1, dated 19.03.2015**	2015-000620-28	alirocumab (SAR236553, REGN727)	Nu	Nu	Afecţiuni cardiovasculare	sanofi-aventis Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	sanofi-aventis groupe	internaţional	A Multi-Country, Multicenter, Single-Arm, Open-Label Study to Document the Safety, Tolerability and Effect of Alirocumab on atherogenic lipoproteins in High Cardio-Vascular Risk Patients With Severe Hypercholesterolemia Not Adequately Controlled With Conventional Lipid-Modifying Therapie	III	15		**28.03.2016**		**09.05.2016**		
335	**AB12010, version ROW 3.0, dated 30.07.2015**	2013-000493-30	masitinib mesylate AB1010	Nu	Nu	Afecţiuni oncologice	HT Research RO SRL Natalia Popa E-mail: naneagoe@hungarotrial.com	AB Science	internaţional	A prospective, multicentre, open-label, randomized, active-controlled, 3 parallel groups, phase 2 study to compare the efficacy and safety of masitinib in combination with FOLFIRI (irinotecan, 5-fluorouracil and folinic acid, versus masitinib alone, versus Best Supportive Care, in third or fourth line treatment of patients with metastatic colorectal cancer	II	20						
336	**GO29527, version 3, dated 05.09.2015 VHP2015080**	2014-003205-15	atezolizumab MPDL3280A RO6541267	Nu	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A Phase III, Open-Label, Randomized Study To Investigate The Efficacy And Safety Of Atezolizumab (Anti-PD-L1 Antibody) Compared With Best Supportive Care Following Adjuvant Cisplatin-Based Chemotherapy In Patients With Completely Resected Stage IB-IIIa Non-Small Cell Lung Cancer	III	6		**14.10.2015**		**29.02.2016**		
337	**42165279MDD2001, version INT-1, dated 31.08.2015**	2015-002007-29	JNJ-42165279-AAA	Nu	Da	Afecţiuni ale sistemului nervos	Johnson & Johnson Romania SRL Matei Alexandru Nica email:mnica@its.jnj.com	Janssen-Cilag International NV	internaţional	A Phase 2a Randomized, Double-blind, Placebo-Controlled, Parallel-Group, Multi-center Study Investigating the Efficacy, Safety, and Tolerability of JNJ-42165279 in Subjects with Major Depressive Disorder with Anxious Distress	II	10						**18.01.2016**
338	**8273-CL-0302, version 1.0, dated 29.07.2015**	2015-002894-39	ASP8273	Iressa® (gefitinib) Tarceva® (erlotinib)	Nu	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Emilia Olteanu E-mail: emilia.olteanu@parexel.com	Astellas Pharma Global Development, Inc.	internaţional	An Open-label, Randomized Phase 3 Efficacy Study of ASP8273 vs Erlotinib or Gefitinib in First-line Treatment of Patients with Stage IIIB/IV Non-small Cell Lung Cancer Tumors with EGFR Activating Mutations	III	27		**13.07.2016**		**24.08.2016**		

339	**NN9924-4222, (version 2.0, dated 24.08.2015 initial) , version 3.0, dated 12.11.2015**	2015-001351-71	semaglutide	Januvia® (sitagliptin)	Da	Afecţiuni nutriţionale şi metabolice	Novo Nordisk Farma SRL Cătălin Bucarzan E-mail: catb@novonordisk.com	Novo Nordisk A/S	internaţional	Efficacy and long-term safety of oral semaglutide versus sitagliptin in subjects with type 2 diabetes	III	132		**21.03.2016**		**05.04.2016**		
340	**GS-US-313-1580, version Original, dated 12.06.2015** **VHP2015091**	2015-000366-66	Zydelig® (idelalisib, GS-1101)	Nu	Da	Afecţiuni oncologice	Pharmaceutical Research Associates Romania SRL Victoria Pirzaru E-mail: pirzaruvictoria@prahs.com	Gilead Sciences, Inc.	internaţional	Dose Optimization Study of Idelalisib in Follicular Lymphoma	III	28		**11.11.2015**				**16.03.2016**
341	**CAIN457A2310, (version 01, dated 01.04.2015 initial), version 02, dated 10.02.2016**	2014-005663-32	Cosentyx® (secukinumab, AIN457)	Etanercept® (etanercept)	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A randomized, double-blind, placebo- and active controlled multicenter trial to demonstrate efficacy of subcutaneous secukinumab compared to placebo and etanercept (in a single blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in subjects from 6 to less than 18 years of age with severe chronic plaque psoriasis	III	6		**07.12.2016**	**07.07.2016**			
342	**RD.06.SPR.18252, version 01, dated 21.07.2015**	2015-002540-13	trifarotene (CD5789)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	Chiltern International Ltd Anne Dickie Email: anne.dickie@chiltern.com Emilia Lungu Emilia.lungu@chiltern.com	Galderma R&D SNC	internaţional	A Multi-Center, Randomized, Double-Blind, Parallel-Group Vehicle Controlled Study To Compare The Efficacy And Safety Of CD5789 50µg/g Cream Versus Vehicle Cream In Subjects With Acne Vulgaris	III	96		**05.05.2016**		**01.06.2016**	**12.05.2017**	
343	**CV181-369, dated 06.07.2015**	2015-001702-33	Onglyza® (saxagliptin) Forxiga® (dapagliflozin)	glargine insulin	Nu	Afecţiuni nutriţionale şi metabolice	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	AstraZeneca AB, Sweden	internaţional	A 24-week International, Multicenter, Randomized, Open-Label, Active-Controlled, Parallel Group, Phase 3b Trial with a 28-week Extension to Evaluate the Efficacy and Safety of Saxagliptin Co-administered with Dapagliflozin Compared to Insulin Glargine in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin with or without Sulfonylurea Therapy	III	40		**15.04.2016**	**10.02.2016**	**22.05.2016**		
344	**SB-2-004-005, version 3.1, dated 29.05.2015**	2015-002346-32	kymerase (SYN-004)	Nu	Da	Infecţii bacteriene şi micoze	HT Research RO SRL Natalia Popa E-mail: naneagoe@hungarotrial.com	Synthetic Biologics, Inc.	internaţional	A Phase 2b Parallel-Group, Double-Blind, Placebo-Controlled, Multicenter Study of SYN-004 Compared to Placebo for the Prevention of Clostridium difficile Associated Diarrhea in Patients with a Diagnosis of a Lower Respiratory Tract Infection	II	100		**18.01.2016**		**08.02.2016**	**10.11.2016**	
345	**GS-US-326-1100, Amendment 1.2, dated 02.10.2015** **VHP2015092**	2014-005217-24	GS-5745	Nu	Da	Afecţiuni ale sistemului digestiv	ICON Clinical Research SRL Alin Balalau E-mail: alin.balalau@iconplc.com	Gilead Sciences, Inc.	internaţional	A Combined Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 in Subjects with Moderately to Severely Active Ulcerative Colitis	II/III	41		**16.11.2015**	**23.12.2015**	**11.02.2016**	**21.09.2016**	
346	**CQVM149B2301, (version 01, dated 30.07.2015 initial) version 02, dated 01.10.2015**	2015-002529-21	indacaterol acetate+mometasone furoate (QMF149)	Asmanex Twisthaler® (mometasone furoate) Seretide® (salmeterol xinafoate+fluticasone propionate)	Nu	Afecţiuni ale tractului respirator	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A multi-center, randomized, 52 week treatment, doubleblind, triple-dummy, parallel-group study to assess the efficacy and safety of QMF149 compared with mometasone furoate in patients with asthma	III	155		**15.04.2016**		**22.06.2016**		
347	**56021927PCR3003, version Initial, dated 14.07.2015**	2015-003007-38	JNJ-56021927	Casodex® (bicalutamide)	Da	Afecţiuni oncologice	Johnson & Johnson Romania SRL Rareş Halţegan E-mail: rhaltegan@its.jnj.com	Janssen-Cilag International NV	internaţional	A Randomized, Double-blind, Placebo-controlled Phase 3 Study of JNJ56021927 in Subjects with High-risk, Localized or Locally Advanced Prostate Cancer Receiving Treatment with Primary Radiation Therapy	III	50		**08.04.2016**	**24.03.2016**			
348	**CCD-05993AB1-03, version 1.0, dated 03.08.2015**	2015-000716-18	CHF 5993 (beclometasone dipropionate+formoterol fumarate+glycopyrronium bromide)	Fostair® (CHF 1535/beclometasone dipropionate+formoterol fumarate)	Nu	Afecţiuni ale tractului respirator	Chiltern International Ltd Nauman Shaheen E-mail: nauman.shaheen@chiltern.com	Chiesi Farmaceutici S.p.A.	internaţional	A 52 week, randomized, double blind, multinational, multicentre, active controlled, 2-arm parallel group trial comparing CHF 5993 100/6/12.5 µg pMDI (fixed combination of extrafine beclometasone dipropionate plus formoterol fumarate plus glycopyrronium bromide) to CHF 1535 100/6 µg pMDI (fixed combination of extrafine beclomethasone dipropionate plus formoterol fumarate) in patients with asthma uncontrolled on medium doses of inhaled corticosteroids in combination with long-acting ß2- agonists	III	177		**30.05.2016**	**01.02.2016**			
349	**APD334-003, Amendment 4, dated 21.09.2015**	2015-001942-28	APD334	Nu	Da	Afecţiuni ale sistemului digestiv	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppd.com	Arena Pharmaceuticals, Inc., SUA	internaţional	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi-Center Study to Investigate the Safety and Efficacy of APD334 in Patients with Moderately to Severely Active Ulcerative Colitis	II	18		**11.08.2016**		**08.12.2016**		
350	**261303, Amendment 3, dated 04.09.2015**	2014-005477-37	BAX 855 (pegylated recombinant Factor VIII, rurioctocog alfa pegol)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	Quintiles Romania SRL Octavia Zamfir E-mail:octavia.zamfir@quintiles.com	Baxalta Innovations GmbH	internaţional	Phase 3, prospective, randomized, multi-center clinical study comparing the safety and efficacy of BAX 855 following PK-guided prophylaxis targeting two different FVIII trough levels in subjects with severe Hemophilia A	III	5		**28.07.2016**				
351	**GX-G3_NHL_2/GX14001, version 1.1, dated 24.08.2015**	2015-002693-20	GX-G3 (pegfilgrastim)	Neulasta® (pegfilgrastim)	Nu	Afecţiuni limfatice şi ale sângelui	Clinical Trial Center SRL Selena Anila Gaia E-mail: selena.boghiu@clinicaltrial.ro	Ilkogen Ilac San. ve Tic. A.S. Turcia	internaţional	A randomized, parallel group, multi-centre phase-2 study of GX-G3 compared with pegfilgrastim as an adjunct to chemotherapy in patients with Non-Hodgkin's Lymphoma	II	15		**18.05.2016**				

352	**AC-AD-003, version 2.0, dated 10.09.2015**	2015-000630-30	AADvac1	Nu	Da	*Afecţiuni ale sistemului nervos*	PPD Romania SRL Manuela Georgiana Botea E-mail: Manuela.Botea@ppdi.com	AXON Neuroscience SE	*internaţional*	"ADAMANT" A 24-months randomised, placebo-controlled, parallel group, double blinded, multi centre, phase 2 study to assess safety and efficacy of AADvac1 applied to patients with mild Alzheimer's disease	II	25		**18.05.2016**	**14.03.2016**	**07.02.2017**		
353	**LP0053-1108, version 2.0, dated 06.07.2015**	2015-000839-33	LEO 90100 (calcipotriol hydrate+betamethasone dipropionate)	Nu	Nu	*Afecţiuni ale pielii şi ţesutului conjunctiv*	Premier Research Romania SRL Ana Popescu E-mail: ana.popescu@premier-research.com	LEO Pharma A/S	*internaţional*	Safety and Effect of LEO 90100 aerosol foam on the HPA Axis and Calcium Metabolism in Adolescent Subjects (Aged 12 to < 17 Years) with Plaque Psoriasis. A phase 2 trial evaluating the safety and efficacy of once daily topical treatment with LEO 90100 aerosol foam in adolescent subjects with plaque psoriasis. An international, multi-centre, prospective, open-label, non-controlled, single-group, 4-week trial in adolescent subjects with plaque psoriasis	II	40		**23.02.2016**		**24.04.2016**		
354	**CQAW039A2307, version 01, dated 19.08.2015**	2015-002553-35	fevipiprant (QAW039)	Nu	Da	*Afecţiuni ale tractului respirator*	PAREXEL International Romania SRL Andreea Flechea E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	*internaţional*	A 52-week, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy and safety of QAW039 when added to existing asthma therapy in patients with uncontrolled severe asthma	III	73		**21.06.2016**		**09.08.2016**		
355	**CB-03-01/27, version 1.0, dated 09.09.2015 initial + CB-03-01_27_pro-Addendum_22Jun2016_v1.0**	2015-002637-21	cortexolone 17alpha-propionate (CB-03-01)	Nu	Nu	*Afecţiuni ale pielii şi ţesutului conjunctiv*	InnoPharma International SRL Massmiliano Stasi E-mail: innopharma@innopharma.it Persoana de contact: Daniela Popescu Email: d.popescu@innopharma.it	CASSIOPEA SpA	*internaţional*	An Open-Label, Long-Term Extension Study to Evaluate the Safety of Cortexolone 17α-Propionate (CB-03-01) Cream, 1% Applied Twice-Daily in Subjects with Acne Vulgaris	III	56		**24.06.2016**	**07.04.2016**			
356	**CL3-20098-076, version Final, dated 01.10.2015**	2015-002181-23	agomelatine Valdoxan® (agomelatine)	Fluoxetine® (fluoxetine)	Da	*Afecţiuni ale sistemului nervos*	HT Research RO Nicoleta Carp E-mail: ncarp@hungarotrial.com	Institut de Recherche International Servier	*internaţional*	Efficacy and safety of 2 doses of agomelatine (10mg, 25mg) given orally in children (from 7 to less than 12 years) and adolescents (from 12 to less than 18 years) with moderate to severe Major Depressive Disorder. A 12-week, randomized, double-blind, active (fluoxetine 10 mg/day with potential adjustment to 20 mg/day) and placebo-controlled, parallel-groups, international, multicentre study followed by an optional open-labelled 21-month safety extension period	III	65		**07.12.2016**				
357	**AP24534-15-303, version 1.0, dated 29.04.2015**	2015-001318-92	ponatinib (AP24534) Iclusig® (ponatinib)	Tasigna® (nilotinib)	Nu	*Afecţiuni limfatice şi ale sângelui*	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com;	ARIAD Pharmaceuticals, Inc.	*internaţional*	A Randomized, Open-label Study of Ponatinib Versus Nilotinib in Patients with Chronic Myeloid Leukemia in Chronic Phase Following Resistance to Imatinib	III	13		**01.07.2016**	**07.07.2016**			
358	**R668-AD-1225, version 04, dated 26.07.2015**	2013-001449-15	dupilumab (REGN668/SAR231893)	Nu	Nu	*Afecţiuni ale pielii şi ţesutului conjunctiv*	PAREXEL International Romania s.r.l. Andreea Flechea E-mail: andreea.flechea@parexel.com	Regeneron Pharmaceuticals, Inc.	*internaţional*	An Open-Label Study of Dupilumab in Patients with Atopic Dermatitis who Participated in Previous Dupilumab Clinical Trials	III	2		**30.03.2016**		**29.06.2016**		
359	**CCD-05993AB2-02, version 1.0, dated 03.08.2015**	2015-000717-40	CHF 5993 pMDI (beclometasone dipropionate + formoterol fumarate + glycopyrronium bromide)	Fostair® (CHF 1535/beclometasone dipropionate+formoterol fumarate) Spiriva Respimat® (tiotropium bromide)	Nu	*Afecţiuni ale tractului respirator*	Chiltern International Ltd Nauman Shaheen E-mail: nauman.shaheen@chiltern.com	Chiesi Farmaceutici S.p.A.	*internaţional*	A 52 week, randomized, double blind, multinational, multicentre, active controlled, 3-arm parallel group trial comparing CHF 5993 200/6/12.5 µg pMDI (fixed combination of extrafine beclometasone dipropionate plus formoterol fumarate plus glycopyrronium bromide) to CHF 1535 200/6 µg pMDI (fixed combination of extrafine beclometasone dipropionate plus formoterol fumarate) alone or on top of open-label tiotropium 2.5 µg Respimat® in patients with asthma uncontrolled on high doses of inhaled corticosteroids in combination with long-acting ß2-agonists	III	195		**01.06.2016**	**08.02.2016**			
360	**ACHN-490-009, dated 23.04.2015 initial) version A1, dated 04.12.2015**	2015-001588-37	plazomicin (ACHN-490, A000008, C001490)	meropenem hydrochloride	Da	*Infecţii bacteriene şi micoze*	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Achaogen, Inc.	*internaţional*	A Phase 3, Randomized, Multicenter, Double-Blind Study to Evaluate the Efficacy and Safety of Plazomicin Compared with Meropenem followed by Optional Oral Therapy for the Treatment of Complicated Urinary Tract Infection (cUTI), including Acute Pyelonephritis (AP), in Adults	III	60		**27.04.2016**	**18.02.2016**	**06.06.2016**	**22.09.2016**	
361	**MIV-711-201, (dated 09.09.2015 initial), Amendment 1, dated 13.01.2016**	2015-003230-26	MIV-711(HCl) (MV076159, CK 1509)	Nu	Da	*Afecţiuni ale sistemului musculo-scheletic*	Arensia Exploratory Medicine SRL Camelia Nita E-mail: camelia.nita@arensia-em.com	Medivir AB	*internaţional*	A Randomised, Double-blind Placebo-controlled Phase IIa Study to Evaluate Efficacy, Safety and Tolerability of MIV-711 in Knee Joint Osteoarthritis	II	7		**16.06.2016**	**23.06.2016**	**01.08.2016**	**26.04.2017**	
362	**CQVA149A2316, version 00, dated 05.06.2015**	2015-000114-22	Ultibro Breezhaler® (indacaterol maleate/glycopyrronium bromide, QVA149)	Seretide® (fluticasone + salmeterol) Spiriva® (tiotropium bromide)	Da	*Afecţiuni ale tractului respirator*	PAREXEL International Romania SRL Mirela Bogdan E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	*internaţional*	A 26-week, randomized, double blind, parallel-group multicenter study to assess the efficacy and safety of QVA149 (110/50 µg o.d.) vs tiotropium (18 µg o.d.) + salmeterol/fluticasone propionate FDC (50/500 µg b.i.d.) in patients with moderate to severe COPD	IV	100		**29.06.2016**		**18.08.2016**		
363	**20140254, (dated 12.06.2015 inmitiali), Amendment 3, dated 27.01.2016**	2015-002322-40	AMG 334	Nu	Da	*Afecţiuni ale sistemului nervos*	Amgen Romania SRL Daniela Stanciu E-mail: daniela.stanciu@amgen.com	Amgen Inc.	*internaţional*	A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Effect of AMG 334 on Exercise Time During a Treadmill Test in Subjects With Stable Angina	II	22		**13.07.2016**		**29.11.2016**	**13.04.2017**	
364	**A4091064, version Final, dated 01.04.2015 VHP2015056-SW1**	2013-002549-12	tanezumab (PF-04383119, R1624, RN624)	Nu	Da	*Afecţiuni ale sistemului musculo-scheletic*	Inventiv Health Clinical Romania srl Irina Copaci E-mail: irina.copaci@inventivhealth.com	Pfizer Inc.	*internaţional*	A phase 3, multicenter, long-term observational study of subjects from Tanezumab studies who undergo a total knee, hip or shoulder replacement	III	2		**13.01.2016**				

365	**EMR100070-005, version 3.0, dated 14.10.2015 VHP2015107**	2015-001537-24	avelumab (MSB0010718C)	Gemcitabine Hospira® (gemcitabine hydrochloride) Paclitaxel Hospira® (paclitaxel) Cisplatin Hospira® (cisplatin) Carboplatin Hospira® (carboplatin) Alimta® (pemetrexed disodium)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Octavia Zamfir E-mail:octavia.zamfir@quintiles.com	Merck KGaA, Germania	internaţional	A Phase III, open-label, multicenter trial of avelumab (MSB0010718C) versus platinum based doublet as a first line treatment of recurrent or Stage IV PD L1+ non small cell lung cancer	III	26		**22.12.2015**		**29.08.2016**		
366	**D419AC00003, Edition 02, dated 21.08.2015 VHP2015108**	2015-002197-21	durvalumab (MEDI4736) tremelimumab (MEDI1123)	Paclitaxel® (paclitaxel) Carboplatin® (carboplatin) Gemcitabine® (gemcitabine) Cisplatin® (cisplatin) Alimta® (pemetrexed)	Nu	Afecţiuni oncologice	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A Phase III Randomized, Open-Label, Multi-Center, Global Study of MEDI4736 in Combination with Tremelimumab Therapy Versus Standard of Care Platinum-Based Chemotherapy in First-Line Treatment of Patients with Advanced or Metastatic Non-Small-Cell Lung Cancer (NSCLC) (NEPTUNE)	III	25		**02.12.2015**				
367	**CCD-06302AA1-01, (version 2.0, dated, 24.09.2015 initial), version 3.0, dated 24.11.2015**	2015-000558-40	Glycopyrronium bromide NEXThaler (glycopyrronium bromide, CHF 5259)	Nu	Da	Afecţiuni ale tractului respirator	Orion Clinical Services Ltd Anisa Abbasi E-mail: anisa.abbasi@orioncro.com	Chiesi Farmaceutici S.p.A.	internaţional	A multicenter, randomised, double blind, placebo-controlled, incomplete block, 3-way cross-over study to evaluate the efficacy and safety of 4 doses of glycopyrronium bromide DPI in moderate to severe patients with chronic obstructive pulmonary disease (COPD)	II	97		**26.05.2016**	**28.03.2016**	**24.06.2016**	**06.02.2017**	
368	**4083-002, Amendment 1, dated 15.10.2015**	2015-001555-69	KHK4083	Nu	Da	Afecţiuni ale sistemului digestiv	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Kyowa Kirin Pharmaceutical Development, Inc.	internaţional	A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled Multiple Ascending Dose Study (Induction Therapy and Long-term Extension Therapy) of an Anti-OX40 Monoclonal Antibody (KHK4083) in Subjects with Moderately Active Ulcerative Colitis	II	6		**30.05.2016**		**22.08.2016**		
369	**I67-MC-AMAC, dated 18.09.2015 and Protocol Addendum (4), dated 02.06.2016**	2015-003123-57	LY3074828	Nu	Da	Afecţiuni ale sistemului digestiv	Arensia Exploratory Medicine SRL Alin Stirbu E-mail: alin.stirbu@arensia-em.com	Eli Lilly and Company	internaţional	A Phase 2, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Study of LY3074828 in Subjects with Moderate to Severe Ulcerative Colitis	II	45		**01.07.2016**				
370	**IM101-550, version rev00a VHP, dated 28.10.2015 VHP2015099**	2015-001275-50	abatacept (BMS-188667)	Methotrexate Ebewe® (methotrexato)	Da	Afecţiuni ale sistemului imunitar	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	A Phase 3B, Randomized, Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of Abatacept SC in Combination with Methotrexate Compared to Methotrexate Monotherapy in Achieving Clinical Remission in Adults with Early Rheumatoid Arthritis who are Methotrexate Naive	III	36		**22.12.2015**	**10.02.2016**	**17.09.2016**		
371	**PM0259CA233B0, version 01, dated 30.01.2015**	2014-003860-19	Navelbine® (vinorelbine tartrate, PM0259)	Navelbine® (vinorelbine tartrate, PM0259)	Nu	Afecţiuni oncologice	Accovion SRL Carmen Vizman E-mail: carmen.vizman@accovion.com	Pierre Fabre Medicament, Franţa	internaţional	Randomised Phase II Study comparing, as first-line chemotherapy, single-agent Oral Vinorelbine administered with two different schedules in patients with Advanced Breast Cancer	II	32		**14.10.2016**		**06.03.2017**		
372	**PM0259CA232J1, version 01, dated 21.01.2015**	2014-003859-61	Navelbine® (vinorelbine tartrate, PM0259)	Navelbine® (vinorelbine tartrate, PM0259)	Nu	Afecţiuni oncologice	Accovion SRL Carmen Vizman E-mail: carmen.vizman@accovion.com	Pierre Fabre Medicament, Franţa	internaţional	Randomized Phase II study comparing single agent oral vinorelbine administered with two different schedules in patients with Advanced Non Small Cell Lung Cancer unfit for a platinum-based chemotherapy	II	28		**14.10.2016**		**28.02.2017**		
373	**0112, Amendment 2, dated 14.09.2015 initial**	2014-004372-27	Vibativ® (telavancin hydrochloride)	vancomycin daptomycin oxacillin cefazolin	Nu	Infecţii bacteriene şi micoze	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Theravance Biopharma Antibiotics, Inc.	internaţional	A Phase 3 Multicenter, Randomized, Open-label, Clinical Trial of Telavancin Versus Standard Intravenous Therapy in the Treatment of Subjects with Staphylococcus aureus Bacteremia Including Infective Endocarditis	III	21		**15.09.2016**				
374	**A0081042, version Final, dated 30.12.2013**	2013-003420-37	Lyrica® (pregabalin)	Nu	Da	Afecţiuni ale sistemului nervos	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Pfizer Inc.	internaţional	A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study Of The Efficacy And Safety Of Pregabalin As Adjunctive Therapy In Children 1 Month Through < 4 Years Of Age With Partial Onset Seizures	III	19		**07.04.2016**	**17.03.2016**	**30.05.2016**		
375	**TP0001, (dated 09.11.2015 initial), Amendament 0.4 (Romania), dated 11.08.2016**	2015-003984-12	UCB7665	Nu	Nu	Afecţiuni limfatice şi ale sângelui	PAREXEL International Romania s.r.l Sinziana Oana E-mail: sinziana.oana@parexel.com	UCB Biopharma SPRL, Belgia	internaţional	A multicenter, open-label, multiple-dose study to evaluate the safety, tolerability, and efficacy of UCB7665 in subjects with primary immune thrombocytopenia	II	6		**29.08.2016**				
376	**AC-061A302, (version 2.A, dated 11.12.2014), version 2.A, dated 11.12.2014 and PRO Sub-study Protocol AC-061A301(302), version 2, dated 11.12.2014 VHP2013096-SW2**	2013-002508-15	cadazolid (ACT-179811)	Vancocin® (vancomycin)	Da	Infecţii bacteriene şi micoze	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppdi.com	Actelion Pharmaceuticals Ltd.	internaţional	A multi-center, randomized, double-blind study to compare the efficacy and safety of cadazolid versus vancomycin in subjects with Clostridium difficile-associated diarrhea (CDAD)	III	120		**28.12.2015**		**23.02.2016**	**02.05.2017**	
377	**A4091057, Amendment 1, dated 13.11.2015 VHP2015109**	2013-004508-21	tanezumab (PF-04383119, R1624, RN624)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	inVentiv Health Clinical Romania SRL Irina Copaci E-mail: irina.copaci@inventivhealth.com	Pfizer Inc.	internaţional	A phase 3 randomized, double-blind, placebo-controlled, multicenter study of the analgesic efficacy and safety of the subcutaneous administration of tanezumab in subjects with osteoarthritis of the hip or knee	III	45		**28.12.2015**		**05.07.2016**		

378	**CQVM149B2302, version 03, dated 08.10.2015**	2015-002899-25	QVM149 (indacaterol acetate+glycopyrronium bromide+mometasone furoate)	QMF149 (indacaterol acetate+mometasone furoate) Seretide® (salmeterol xinafoate+fluticasone propionate)	Da	Afecţiuni ale tractului respirator	Parexel International Romania SRL Andreea Flechea E-mail: europe.cta@novartis.com	Novartis Pharma Services AG	internaţional	A multicenter, randomized, 52-week, double-blind, parallelgroup, active controlled study to compare the efficacy and safety of QVM149 with QMF149 in patients with asthma	III	100		**29.08.2016**		**04.10.2016**		
379	**GS-US-283-1062, version 0.1, dated 08.09.2015**	2015-002017-30	GS-9620 Viread® (tenofovir disoproxil fumarate)	Nu	Da	Afecţiuni virale	Pharmaceutical Research Associates Romania SRL Andreia Avornicului E-mail: avornicului.andreia@prahs.com	Gilead Sciences, Inc.	internaţional	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-center Study to Evaluate the Safety and Efficacy of GS-9620 in combination with Tenofovir Disoproxil Fumarate (TDF) for the Treatment of Subjects with Chronic Hepatitis B and who are currently not on Treatment	II	20		**04.07.2016**	**19.04.2016**		**04.07.2016**	
380	**GED-0301-CD-002, dated 23.09.2015**	2015-001925-18	mongersen (GED-0301)	Nu	Da	Afecţiuni ale sistemului digestiv	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Celgene Corporation	internaţional	A Phase 3, randomized, double-blind, placebo-controlled, multicenter study to investigate the efficacy and safety of mongersen (GED-0301) for the treatment of subjects with active Crohn's disease	III	35		**27.06.2016**				
381	**GED-0301-CD-004, dated 11.09.2015**	2015-001963-37	mongersen (GED-0301)	Nu	Da	Afecţiuni ale sistemului digestiv	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Celgene Corporation	internaţional	A Phase 3, long-term active treatment extension study of mongersen (GED-0301) in subjects with Crohn's disease	III	35		**29.06.2016**				
382	**ML-3341-306, (version Original, dated 03.09.2015), version Amendament 1, dated 15.12.2015**	2015-003026-14	delafloxacin (RX-3341-83)	moxifloxacin linezolid	Da	Afecţiuni ale tractului respirator	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Melinta Therapeutics, Inc.	internaţional	A phase 3, multicenter, randomized, double-blind, comparator-controlled study to evaluate the safety and efficacy of intravenous to oral delafloxacin in adult subjects with community-acquired bacterial pneumonia	III	69		**31.08.2016**		**13.03.2017**		
383	**EFC13957, (version 1, dated 16.10.2015 initial), version amd 1, dated 29.01.2016**	2015-002084-42	Toujeo® (insulin glargine, HOE901-U300)	Lantus SoloStar® (insulin glargine)	Nu	Afecţiuni nutriţionale şi metabolice	Sanofi Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	sanofi-aventis recherche & développement	internaţional	6-Month, Multicenter, Randomized, Open-label, 2-Arm, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® Injected Once Daily in Children and Adolescents age 6 - 17 Years with Type 1 Diabetes Mellitus with a 6-month Safety Extension Period	III	31		**23.08.2016**	**25.07.2016**			
384	**EMR100070-008, (version 3.0, dated 22.10.2015 initial), version 5.0, dated 29.04.2016**	2015-003301-42	avelumab (MSB0010718C)	Irinotecan® (irinotecan) Paclitaxel® (paclitaxel)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Merck KGaA	internaţional	A Phase III open-label, multicenter trial of avelumab (MSB0010718C) as a third-line treatment of unresectable, recurrent, or metastatic gastric or gastroesophageal junction adenocarcinoma	III	60		**30.09.2016**		**31.10.2016**		
385	**GS-US-330-1509, Amendment 1, dated 11.03.2015**	2015-001050-16	Viread® (tenofovir disoproxil fumarate) Pegasys® (peginterferon alfa-2a) GS-4774 GS-9620	Nu	Nu	Afecţiuni virale	Pharmaceutical Research Associates Romania SRL Victoria Pinzaru E-mail: pinzaruvictoria@prahs.com	Gilead Sciences, Inc.	internaţional	A Long Term Follow-up Registry of Subjects Treated in A Gilead-Sponsored Trial in Subjects with Chronic Hepatitis B Infection	II	9		**11.08.2016**				
386	**E7080-G000-211, Amendment 1, dated 01.12.2015 VHP2015120**	2014-005199-27	Lenvima® (lenvatinib, E7080)	Nu	Da	Afecţiuni oncologice	PPD Romania S.R.L. Corina Avramescu E-mail: Corina.Avramescu@ppdi.com	Eisai Limited	internaţional	A Multicenter, Randomized, Double-blind Phase 2 Trial of Lenvatinib (E7080) in Subjects with 131I Refractory Differentiated Thyroid Cancer to Evaluate Whether an Oral Starting Dose of 20 mg or 14 mg Daily Will Provide Comparable Efficacy to a 24-mg Starting Dose, But Have a Better Safety Profile	II	8		**11.01.2016**	**07.03.2016**	**26.05.2016**		**29.07.2016**
387	**SHP616-300, (version 3.0, dated 03.09.2015 initial), version 4.0, dated 11.01.2016**	2015-002478-19	C1 esterase inhibitor (SHP616) Firazyr® (icatibant)	Nu	Da	Afecţiuni cardiovasculare	PPD Romania SRL Elena Calina E-mail: elena.calina@ppdi.com	Shire ViroPharma, Inc.	internaţional	A Phase 3, Randomized, Double-blind, Placebo-controlled, Two-period, Three-sequence, Partial Crossover Study to Evaluate the Efficacy and Safety of Subcutaneous Administration of 2000 U of C1 Esterase Inhibitor [Human] Liquid for Injection for the Prevention of Angioedema Attacks in Adolescents and Adults with Hereditary Angioedema	III	7		**04.07.2016**		**10.08.2016**		
388	**MK-0887A-087, version 00, dated 13.08.2015**	2009-010110-30	MK-0887A (SCH418131, mometasone furoate+formoterol fumarate MDI)	MK-0887 (SCH032088, mometasone furoate MDI)	Nu	Afecţiuni ale tractului respirator	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A phase III, randomized, active-controlled, parallel-group clinical trial to study the efficacy and long-term safety of mometasone furoate / formoterol fumarate (MF/F, MK-0887A [SCH418131]), compared with mometasone furoate (MF, MK-0887 [SCH032088]), in children with persistent asthma	III	12		**24.03.2016**	**30.05.2016**	**10.07.2016**		
389	**TO-TAS-102-302, Amendment 0.1, dated 16.07.2015**	2015-002683-16	Lonsurf® (trifluridine+tipiracil)	Nu	Da	Afecţiuni oncologice	United Biosource Corporation Federica Vinciati E-mail: federica.vinciati@ubc.com	Taiho Oncology, Inc.	internaţional	Randomized, double-blind, phase 3 study evaluating TAS-102 plus best supportive care (BSC) versus placebo plus BSC in patients with metastatic gastric cancer refractory to standard treatments	III	12		**07.10.2016**				
390	**CA209-451, version revprot00a, dated 24.11.2015 VHP2015121**	2015-002441-61	nivolumab (BMS-936558) ipilimumab (BMS-734016)	Nu	Da	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgium	internaţional	A Randomized, Multicenter, Double-Blind, Phase 3 Study of Nivolumab, Nivolumab in Combination with Ipilimumab, or Placebo as Maintenance Therapy in Subjects with Extensive-Stage Disease Small Cell Lung Cancer (ED-SCLC) after Completion of Platinum-based First Line Chemotherapy	III	20		**26.01.2016**	**25.02.2016**	**05.04.2016**		

391	**A4091061, Amendment 1, dated 18.08.2015 VHP2015072-SW1**	2013-002223-42	tanezumab (PF-04383119, RI624, RN624)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	inVentiv Health Clinical Romania SRL Nicoleta Oropeza Soria E-mail: nicoleta.oropezasoria@inventivhealth.com	Pfizer Inc.	internaţional	A phase 3 randomized, double-blind, placebo-controlled, multicenter study of the analgesic efficacy and safety of the subcutaneous administration of Tanezumab (PF-04383119) in subjects with cancer pain predominantly due to bone metastasis receiving background opioid therapy	III	16		**13.01.2016**	**25.04.2016**	**08.12.2016**		
392	**201810, version 02, dated 06.11.2015**	2015-002361-32	Nucala® (mepolizumab, SB240563)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) Romania SRL Andreea Manuela Cristescu E-mail: andreea.m.cristescu@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	A multi-center, randomized, double-blind, placebo controlled, parallel group study to compare cessation versus continuation of long-term mepolizumab treatment in patients with severe eosinophilic asthma (201810)	III	22		**24.06.2016**		**19.07.2016**		
393	**H-030-014, (version 5.0, dated 28.05.2014 initial), version 7.0 (Amendment 6), dated 14.02.2017**	2013-000775-32	Clostridium difficile Toxoid Vaccine (toxoids A and B)	Nu	Da	Infecţii bacteriene şi micoze	Sanofi Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	Sanofi Pasteur Inc. USA	internaţional	Efficacy, Immunogenicity, and Safety Study of Clostridium difficile Toxoid Vaccine in Subjects at Risk for C. difficile Infection (Cdiffense™)	III	600		**09.06.2017**				
394	**D419LC00001, Edition 3, dated 01.12.2015 VHP2015122**	2015-003589-10	durvalumab (MEDI4736) tremelimumab (MEDI1123)	cetuximab carboplatin 5-fluorouracil (5FU) cisplatin	Nu	Afecţiuni oncologice	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB	internaţional	A Phase III Randomized, Open-label, Multi-center, Global Study of MEDI4736 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	III	27		**10.03.2016**				**21.09.2016**
395	**ICL-24-ABSSSI2, version 01, dated 03.12.2015**	2015-002687-16	iclaprim/iclaprim mesylate (MTF-100 / MTF-100.001)	vancomycin hydrochoride for injection	Nu	Infecţii bacteriene şi micoze	Covance Clinical & Periapproval Services Limited Andreea Curca E-mail: Andreea.Curca@covance.com	Motif BioSciences	internaţional	A Phase 3, randomized, double-blind, multicenter study to evaluate the safety and efficacy of intravenous iclaprim versus vancomycin in the treatment of acute bacterial skin and skin structure infections suspected or confirmed to be due to Gram-positive pathogens. REVIVE-2	III	75		**07.09.2016**		**13.10.2016**		
396	**APD334-005, Amendment 2, dated 28.09.2015**	2015-002109-12	APD334	Nu	Da	Afecţiuni ale sistemului digestiv	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppdi.com	Arena Pharmaceuticals, Inc., SUA	internaţional	An Extension Study of APD334-003 in Patients with Moderately to Severely Active Ulcerative Colitis	II	18		**20.12.2016**				
397	**GS-US-296-1080, version Amendment 3, dated 14.12.2015 VHP2015149**	2015-001526-42	GS-5745	Nu	Da	Afecţiuni oncologice	ICON Clinical Research SRL Alin Bălăiţău E-mail: ICONRomania@iconplc.com	Gilead Sciences, Inc.	internaţional	A Phase 3 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	III	30		**22.02.2016**		**16.05.2016**		
398	**MBCT206, (version Final, dated 23.12.2015 initial), version Final 3.0, dated 10.03.2016**	2015-004631-13	acumapimod (BCT197)	Nu	Da	Afecţiuni ale tractului respirator	ICON Clinical Research SRL Alin Bălăiţău E-mail: ICONRomania@iconplc.com	Mereo BioPharma 1 Ltd.	internaţional	A Phase IIa, two-part, randomised, multi-centre, multinational, double-blind, placebo-controlled, parallel group study to compare the efficacy and safety of BCT197 when added on to standard of care for the treatment of acute respiratory exacerbations of chronic obstructive pulmonary disease (COPD) requiring hospitalisation in adults	II	21		**14.09.2016**	**30.05.2016**	**02.11.2016**		
399	**20140355 (CFZ014), Amendment 2.0, dated 28.04.2015**	2014-005325-12	Kyprolis® (carfilzomib, PR-171)	Nu	Nu	Afecţiuni oncologice	Amgen Romania SRL Daniela Stanciu E-mail: daniela.stanciu@amgen.com	Onyx Therapeutics, Inc.	internaţional	A Randomized, Open-label, Phase 3 Study in Subjects with Relapsed and Refractory Multiple Myeloma Receiving Carfilzomib in Combination with Dexamethasone, Comparing Once-weekly versus Twice-weekly Carfilzomib Dosing	III	9		**25.04.2016**		**22.06.2016**		
400	**F-FR-00250-105, version Final, dated 25.01.2016**	2015-001138-10	Diosmectite Beaufour® (diosmectite)	Nu	Da	Afecţiuni ale sistemului digestiv	KCR S.A. Adriana Rusu E-mail: adriana.rusu@kcrcro.com	Ipsen Pharma SAS	internaţional	Efficacy of diosmectite (Smectal®) in the symptomatic treatment of acute diarrhoea in adults. A multicentre, randomised, double-blind, placebo-controlled, parallel groups study	IV	100		**07.09.2016**				
401	**D-FR-52120-222, version 1.0, dated 14.09.2015**	2015-003471-30	Dysport® (Clostridium botulinum toxin type A)	Nu	Da	Hiperactivitatea detrusorului de origine neurologică	Covance Clinical & Periapproval Services Limited Loredana Rădulescu E-mail: loredana.radulescu@covance.com	Ipsen Innovation	internaţional	A phase III, multicentre, randomised, double blind, parallel group, placebo controlled study to assess the efficacy and safety of one or more intradetrusor treatments of 600 or 800 units of Dysport® for the treatment of urinary incontinence in subjects with neurogenic detrusor overactivity due to spinal cord injury or multiple sclerosis	III	27		**26.09.2016**	**09.06.2016**	**14.11.2016**		
402	**EMR100070-007, (version 2.0, dated 23.09.2015 initial), version 3.0, dated 06.01.2016**	2015-003300-23	avelumab (MSB0010718C)	Capecitabine Accord® (capecitabine) Oxaliplatin Hospira® (oxaliplatin) Fluorouracil Hospira® (fluorouracil)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Merck KGaA, Germany	internaţional	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	III	37		**07.10.2016**		**29.11.2016**		
403	**OOC-ACM-302, version 2.0, dated 30.11.2015**	2015-002854-11	octreotide (Mycapssa®)	Sandostatin LAR® (octreotide) Somatuline Autogel® (lanreotide)	Nu	Afecţiuni hormonale	Pharm-Olam International (UK) Ltd. Ramona Nicolescu E-mail: ramona.nicolescu@pharm-olam.com	Chiasma, Inc.	internaţional	A phase 3, randomized, open-label, active controlled, multicenter study to evaluate maintenance of response, safety and patient reported outcomes in Acromegaly patients treated with Octreotide capsules, and in patients treated with standard of care parenteral somatostatin receptor ligands who previously tolerated and demonstrated a biochemical control on both treatments	III	10		**15.11.2016**				**09.12.2016**

404	**AB11003, version 7.1, dated 20.10.2015**	2012-004222-25	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni ale sistemului digestiv	HT Research RO SRL Andreea Zaharia E-mail: azaharia@hungarotrial.com	AB Science	internaţional	A 12-week with possible extension, prospective, multicenter, randomised, double-blind, controlled, 2-parallel groups, phase 2b/3 study to compare efficacy and safety of masitinib to placebo, in the treatment of moderate Crohn's disease in patients intolerant or with unsatisfactory response to immunosuppressive drugs and/or TNF-inhibitors	II	30							
405	**PENTA 17, version 1.1, dated 26.05.2015**	2013-001476-37	Norvir® (ritonavir) Prezista® (darunavir) Vitekta® (elvitegravir)	Nu	Nu	Afecţiuni virale	Fundatia Romania Angel Appeal (RAA) Silvia Asandi E-mail: silvia.asandi@raa.ro	Fondazione PENTA ONLUS	internaţional	SMILE: Strategy for Maintenance of HIV suppression with elvitegravir+darunavir/ritonavir in children (PENTA 17) - A two-arm, Phase 2/3 multicentre, open-label, randomised study evaluating safety and antiviral effect of current standard antiretroviral therapy compared to elvitegravir (EVG) administered with darunavir/ritonavir (DRVr) in HIV-1 infected, virologically suppressed paediatric participants	II/III	6							
406	**GO29438, version 2, dated 24.11.2015**	2015-003605-42	atezolizumab (Ro 554-1267/F03-01, MPDL3280A)	Alimta® (pemetrexed)	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Colpcaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Switzerland	internaţional	A Phase III, Open-Label, Randomized Study of Atezolizumab (MPDL3280A, ANTI-PD-L1 Antibody) in Combination With Carboplatin or Cisplatin+Pemetrexed Compared with Carboplatin or Cisplatin+Pemetrexed in Patients who are Chemotherapy-Naive and Have Stage IV Non-Squamous Non−Small Cell Lung Cancer	III	60		**11.11.2016**		**21.12.2016**			
407	**I1F-MC-RHBX, dated 18.01.2016**	2015-003938-27	ixekizumab (LY2439821)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company	internaţional	A 52 Week Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of Ixekizumab (LY2439821) in SCMARD Naive Patients with Nonradiographic Axial Spondyloarthritis	III	13		**25.08.2016**	**27.06.2016**	**27.09.2016**			
408	**178-CL-206A, version 1.0, dated 09.12.2015**	2015-002876-25	Betmiga® (mirabegron)	Nu	Nu	Hiperactivitatea detrusorului de origine neurologică	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Astellas Pharma Europe B.V.	internaţional	An Open-label, Baseline-controlled, Multicenter, Phase 3 Dose-titration Study Followed by a Fixed-dose Observation Period to Evaluate Efficacy, Safety and Pharmacokinetics of Mirabegron in Children and Adolescents From 5 to Less Than 18 Years of Age With Neurogenic Detrusor Overactivity (NDO) on Clean Intermittent Catheterization (CIC)	III	4		**08.11.2016**	**26.05.2016**	**16.01.2017**			
409	**SB8-G31-NSCLC, Amendment 1.0, dated 17.12.2015**	2015-004026-34	SB8 (proposed bevacizumab biosimilar)	Avastin® (bevacizumab)	Nu	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Andrada Ciorobitca E-mail: andrada.ciorobitca@parexel.com	Samsung Bioepis Co., Ltd., Korea	internaţional	A Phase III, Randomised, Double-blind, Multicentre Study to Compare the Efficacy, Safety, Pharmacokinetics and Immunogenicity between SB8 (proposed bevacizumab biosimilar) and Avastin® in Subjects with Metastatic or Recurrent Non-squamous Non-small Cell Lung Cancer	III	87		**16.09.2016**		**26.10.2016**			
410	**200812, version 01, dated 25.01.2016**	2015-005212-14	fluticasone furoate/umeclidinium bromide/vilanterol trifenatate (GW685698/GSK573719/GW642444) Relvar Ellipta® (fluticasone furoate/vilanterol trifenatate, GW685698/GW642444) Incruse® (umeclidinium bromide, GSK573719)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) Romania SRL Mirela Chiricescu E-mail: mirela.g.chiricescu@gsk.com	GlaxoSmithKline Research & Development Ltd.	internaţional	A phase IIIB, 24-week randomised, double-blind study to compare 'closed' triple therapy (FF/UMEC/VI) with 'open' triple therapy (FF/VI + UMEC), in subjects with chronic obstructive pulmonary disease (COPD)	III	84		**04.08.2016**	**07.06.2016**	**18.08.2016**	**28.04.2017**		
411	**16159A, version 1.0, dated 01.12.2015**	2014-003569-12	AF35700	olanzapine risperidone	Nu	Afecţiuni ale sistemului nervos	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	H. Lundbeck A/S	internaţional	Interventional, randomised, double-blind, active-controlled, fixed-dose study of Lu AF35700 in patients with Treatment-resistant Schizophrenia	III	85		**07.10.2016**		**14.03.2017**			
412	**261203, Amendment 2, dated 16.10.2015**	2015-002136-40	PEGylated rFVIII (BAX855)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Baxalta Innovations GmbH	internaţional	Phase 3, prospective, multi-center, open label study to investigate safety, immunogenicity, and hemostatic efficacy of PEGylated Factor VIII (BAX 855) in previously untreated patients (PUPs) < 6 years with severe hemophilia A (FVIII < 1%)	III	2		**07.10.2016**					
413	**CAIN457A3401, version 00, dated 21.10.2015**	2015-003701-42	Cosentyx® (secukinumab, AIN457)	Nu	Nu	Afecţiuni ale pielii şi ţesutului conjunctiv	PAREXEL International Romania s.r.l. Victor Seremet E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	An open-label, prospective, non-randomized, multicenter study to evaluate clear skin effect on health related quality of life outcomes at 16 and 52 weeks in patients with moderate to severe plaque psoriasis treated with secukinumab 300 mg s.c. with or without previous exposure to systemic therapy	IV	40		**20.12.2016**	**18.10.2016**	**08.02.2017**			
414	**9785-CL-0335, (version 1.0, dated 10.11.2015 initial), version 2.0, dated 02.06.2016**	2015-003869-28	Xtandi® (enzalutamide, MDV3100)	Nu	Da	Afecţiuni oncologice	PPD Romania SRL Ana Andreea Draghici E-mail: ana.draghici@ppdi.com	Astellas Pharma Global Development, Inc (APGD)	internaţional	A Multinational, Phase 3, Randomized, Double-blind, Placebo-controlled Efficacy and Safety Study of Enzalutamide Plus Androgen Deprivation Therapy (ADT) Versus Placebo Plus ADT in Patients with Metastatic Hormone Sensitive Prostate Cancer (mHSPC)	III	48		**31.10.2016**		**06.01.2017**			
415	**BAY94-8862/17530, version 1.0, dated 10.06.2015**	2015-000950-39	finerenone (BAY 94-8862)	Nu	Da	Afecţiuni cardiovasculare	SC BAYER SRL Corina Carpa-veche E-mail: ra_romania@bayer.com	Bayer AG (BAG)	internaţional	A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone on the reduction of cardiovascular morbidity and mortality in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease in addition to standard of care	III	162		**03.11.2016**	**22.09.2016**	**07.11.2016**			
416	**BAY94-8862/16244, version 1.0, dated 10.06.2015**	2015-000990-11	finerenone (BAY 94-8862)	Nu	Da	Afecţiuni cardiovasculare	SC BAYER SRL Corina Carpa-veche E-mail: ra_romania@bayer.com	Bayer AG (BAG)	internaţional	A randomized, double-blind, placebo-controlled, parallel-group, multicenter, event-driven Phase III study to investigate the efficacy and safety of finerenone, in addition to standard of care, on the progression of kidney disease in subjects with type 2 diabetes mellitus and the clinical diagnosis of diabetic kidney disease	III	187		**03.11.2016**	**22.09.2016**	**10.11.2016**			

417	**WO29522, version 4, dated 20.11.2015**	2014-005490-37	atezolizumab (MPDL3280A-RO5541267-F-03)	Abraxane® (paclitaxel, RO024-7506)	Da	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	A Phase III, Multicenter, Randomized, Placebo-Controlled Study of Atezolizumab (ANTI-PD-L1 Antibody) in Combination with Nab-Paclitaxel Compared with Placebo with Nab-Paclitaxel for Patients with Previously Untreated Metastatic Triple-Negative Breast Cancer	III	6		**16.11.2016**	**27.07.2016**	**20.03.2017**		
418	**SB3-G31-BC-E, version 1.0, dated 17.12.2015**	2015-005663-17	SB3 (trastuzumab biosimilar)	Herceptin® (trastuzumab)	Nu	Afecţiuni oncologice	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Samsung Bioepis Co., Ltd.	internaţional	A Long-term Follow-up Study for Cardiac Safety in the Patients with HER2 Positive Early or Locally Advanced Breast Cancer Who Have Completed the SB3-G31-BC	III	38		**17.11.2016**		**22.12.2016**		
419	**V118_19, (version 3, dated 16.12.2015 initial), version 4, dated 29.03.2016**	2015-000728-27	Adjuvanted Quadrivalent Influenza Vaccine (aQIV)-surface antigen, inactivated, adjuvanted with MF59 aQIV	Boostrix® (Diphteria, Tetanus and Pertussis vaccine)	Nu	Afecţiuni virale	PAREXEL International Romania s.r.l. Florentina Berlic E-mail: Florentina.Berlic@parexel.com	Seqirus UK Limited	internaţional	A Phase III, Randomized, Observer-Blind, Controlled, Multicenter Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of an MF59-Adjuvanted Quadrivalent Influenza Vaccine Compared to Non-influenza Vaccine Comparator in Adults ≥ 65 Years of Age	III	1050		**18.11.2016**	**28.07.2016**	**05.12.2016**		
420	**1014802-203, (version 2, dated 03.03.2016 initial), version 3, dated 28.07.2016**	2015-004775-78	raxatrigine (BIIB074)	Nu	Da	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor- eugen.almasan@quintiles.com	Convergence Pharmaceuticals Ltd.	internaţional	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of BIIB074 in Subjects With Neuropathic Pain From Lumbosacral Radiculopathy	II	75		**18.11.2016**		**23.01.2017**		
421	**MLN0002SC-3027, version 02, dated 10.02.2016 VHP2015163**	2015-000480-14	vedolizumab (MLN0002)	Nu	Da	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Takeda Development Centre Europe, Ltd.	internaţional	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study, with a Vedolizumab IV Reference Arm, to Evaluate the Efficacy and Safety of Vedolizumab Subcutaneous as Maintenance Therapy in Subjects With Moderately to Severely Active Ulcerative Colitis Who Achieved Clinical Response Following Open-Label Vedolizumab Intravenous Therapy	III	6		**04.04.2016**		**15.09.2016**		
422	**MLN0002SC-3030, version 02, dated 10.02.2016 VHP2015164**	2015-000482-31	vedolizumab (MLN0002)	Nu	Nu	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Takeda Development Centre Europe, Ltd.	internaţional	A Phase 3b Open-label Study to Determine the Long-term Safety and Efficacy of Vedolizumab Subcutaneous in Subjects with Ulcerative Colitis and Crohn's Disease	III	9		**04.04.2016**				
423	**MLN0002SC-3031, version 02, dated 10.02.2016 VHP2015165**	2015-000481-58	vedolizumab (MLN0002)	Nu	Da	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Takeda Development Centre Europe, Ltd.	internaţional	A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Vedolizumab Subcutaneous as Maintenance Therapy in Subjects With Moderately to Severely Active Crohn's Disease Who Achieved Clinical Response Following Open-Label Vedolizumab Intravenous Therapy	III	12		**04.04.2016**		**24.08.2016**		
424	**BV-NSCLC-002, version 2.0, dated 28.07.2014**	2013-005335-25	rEGF-rP64k-Montanide ISA 51 VG (epidermal growth factor cancer vaccine) Cyclophosphamide® (ciclofosfamida)	Nu	Nu	Afecţiuni oncologice	EASTHORN CLINICAL SERVICES IN CEE Romania Irina Copaci E-mail: irina.copaci@easthorn.eu	Bioven (Europe) Ltd.	internaţional	A Phase III, open-label, multicentre, randomised trial to establish safety and efficacy of an EGF cancer vaccine in inoperable, late stage IV biomarker positive, wild type EGF-R, NSCLC patients eligible to receive standard treatment and supportive care	III	20		**13.07.2017**				
425	**FER-Loxapine-2015-01, version 3.0, dated 18.12.2015**	2015-003331-36	Adasuve® (loxapine)	Nu	Nu	Afecţiuni ale sistemului nervos	SC Dokumeds CRO SRL Luminita Neferu E-mail: luminita.neferu@dokumeds.com	FERRER INTERNACIONAL SA	internaţional	A Phase IV, Open-label, Non-randomized, Clinical Trial to Evaluate the Safety of self-administered ADASUVE(R) (Staccato loxapine for inhalation) in Agitated Patients outside the hospital setting	IV	17		**21.10.2016**	**26.07.2016**		**26.07.2017**	
426	**I4V-MC-JAHH, dated 11.12.2015 VHP2015183**	2015-004404-35	baricitinib (LY3009104)	Nu	Da	Afecţiuni ale sistemului imunitar	Eli Lilly Romania SRL Luminita Butnaru E-mail: butnaru_luminita@lilly.com	Eli Lilly and Company	internaţional	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 2 Study of Baricitinib in Patients with Systemic Lupus Erythematosus (SLE)	II	15		**07.04.2016**		**05.05.2016**		
427	**NN9924-4221, version 3.0, dated 12.02.2016**	2015-003563-10	semaglutide	Nu	Da	Afecţiuni nutriţionale şi metabolice	Novo Nordisk Farma SRL Cătălin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S, Danemarca	internaţional	A trial investigating the cardiovascular safety of oral semaglutide in subjects with type 2 diabetes	III	100		**26.07.2016**		**13.02.2017**		
428	**MB102138 (D1690C00017), version 2, dated 15.01.2016**	2015-005041-31	Forxiga® (dapagliflozin)	Nu	Da	Afecţiuni nutriţionale şi metabolice	PRA Romania SRL Victoria Pirzaru E-mail: pirzaruvictoria@prahs.com	AstraZeneca AB	internaţional	A 24 Week, Multicenter, Randomized, Double-Blind, Parallel Group, Phase 3 Trial with a 28 Week Long Term Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 10 mg in T2DM Patients aged 10-24 years	III	15		**28.11.2016**	**24.08.2016**	**23.03.2017**		
429	**ARB-001467-002, version 1.1, dated 15.03.2016**	2015-005136-18	ARB-001467 (T05M)	Nu	Da	Afecţiuni virale	Arensia Exploratory Medicine SRL Camelia Ionela Nita E-mail: camelia.nita@arensia-em.com	Arbutus Biopharma Corporation	internaţional	A Phase 1b/2a, Single-Blind, Randomized, Placebo-Controlled Study Evaluating the Safety, Anti-Viral Activity, and Pharmacokinetics of ARB-001467 in Non-Cirrhotic, HBsAg-Negative and Positive Subjects with Chronic HBV Infection Receiving Nucleos(t)ide Analogue Therapy	II	12		**20.04.2016**		**04.05.2016**		

430	**GP17-302, version 3.0, dated 15.02.2016 VHP2015181**	2015-003433-10	adalimumab (GP2017)	Humira® (adalimumab)	Nu	*Afecţiuni ale sistemului imunitar*	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Hexal, AG	*internaţional*	A randomized, double-blind, parallel-group, multicenter study to demonstrate similar efficacy and to compare safety and immunogenicity of GP2017 and Humira® in patients with moderate to severe active rheumatoid arthritis	III	25		**13.04.2016**		**21.07.2016**		
431	**CA209-274, revised 1a, dated 03.03.2016 VHP2015177**	2014-003626-40	nivolumab (BMS-936558)	Nu	Da	*Afecţiuni oncologice*	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	*internaţional*	A Phase 3 Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab versus Placebo in Subjects with High Risk Invasive Urothelial Carcinoma	III	13		**07.04.2016**	**05.05.2016**	**30.06.2016**		
432	**LPS13931, version 1, dated 12.06.2015**	2015-001831-18	Toujeo® (insulin glargine, HOE901 - U300)	standard of care insulin	Nu	*Afecţiuni nutriţionale şi metabolice*	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	sanofi-aventis Groupe	*internaţional*	A twenty six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of Toujeo® compared to standard of care insulin for initiating basal insulin in insulin naïve patients with uncontrolled type 2 diabetes mellitus, with 6 month extension	IV	110		**08.07.2016**				
433	**LPS14060, version 1, dated 12.06.2015**	2015-001832-39	Toujeo® (insulin glargine, HOE901 - U300)	standard of care insulin	Nu	*Afecţiuni nutriţionale şi metabolice*	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	sanofi-aventis Groupe	*internaţional*	A twenty-six week, randomized, open-label, 2-arm parallel group real world pragmatic trial to assess the clinical and health outcomes benefit of transition to Toujeo compared to standard of care insulin, in basal insulin treated patients with uncontrolled type 2 diabetes mellitus, with six month extension	IV	110		**29.07.2016**	**18.04.2016**	**25.08.2016**		
434	**SA-309JG, version 6.1AB, dated 21.03.2016**	2015-005431-41	sapelizumab (SA237)	Nu	Da	*Afecţiuni ale sistemului nervos*	PAREXEL International Romania s.r.l. Cristina Manoliu E-mail: cristina.manoliu@parexel.com	Chugai Pharmaceutical Co. Ltd	*internaţional*	A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy and Safety of SA237 as Monotherapy in Patients With Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorder (NMOSD)	III	3		**07.12.2016**				
435	**DAL-301, dated 18.08.2015**	2015-003895-65	dalcetrapib	Nu	Da	*Afecţiuni cardiovasculare*	August Research SRL Andreea Cătălina Stoenescu E-mail: cstoenescu@augustresearch.com	DalCor Pharma UK Ltd, Altrincham, Swiss Branch Zug, Elveţia	*internaţional*	A phase III, double-blind, randomized placebo-controlled study to evaluate the effects of dalcetrapib on cardiovascular (CV) risk in a genetically defined population with a recent Acute Coronary Syndrome (ACS): The dal-GenE trial	III	149		**19.12.2016**	**29.09.2016**	**06.02.2017**		
436	**IPI-145-22, dated 26.02.2016 VHP2015176**	2015-004033-28	duvelisib (IPI-145)	MabTherall® (rituximab) Levactil® (bendamustine hydrochloride)	Da	*Afecţiuni oncologice*	INC Research Romania SRL Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Infinity Pharmaceuticals, Inc.	*internaţional*	A Phase 3, Randomized, Double-blind Study of Duvelisib Administered in Combination with Rituximab and Bendamustine vs Placebo Administered in Combination with Rituximab and Bendamustine in Subjects with Previously-Treated Indolent Non-Hodgkin Lymphoma	III	20		**30.05.2016**		**28.06.2016**		
437	**MOR208C204, version 3.0, dated 04.03.2016 VHP2016011**	2014-004689-11	MOR00208	MabTherall® (rituximab) Levactil® (bendamustine hydrochloride)	Nu	*Afecţiuni oncologice*	ICON Clinical Research SRL Alin Bălăiţău E-mail: ICONRomania@iconplc.com	MorphoSys AG	*internaţional*	A Phase II/III, Randomised, Multicentre Study of MOR00208 with Bendamustine versus Rituximab with Bendamustine in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R-R DLBCL) Who Are Not Eligible for High-Dose Chemotherapy (HDC) and Autologous Stem-Cell Transplantation (ASCT) – B-MIND	II/III	12		**12.05.2016**				
438	**AC220-A-U302, version 1.0, dated 17.12.2015**	2015-004856-24	quizartinib (AC220)	Nu	Da	*Afecţiuni oncologice*	Covance Clinical & Periapproval Services Limited Andreea Curca	Daiichi Sankyo, Inc.	*internaţional*	A Phase 3, Double-Blind, Placebo-controlled Study of Quizartinib Administered in Combination with Induction and Consolidation Chemotherapy, and Administered as Maintenance Therapy in Subjects 18 to 75 Years Old with Newly Diagnosed FLT3-ITD (+) Acute Myeloid Leukemia (QuANTUM-First)	III	19		**07.12.2016**	**29.09.2016**	**06.02.2017**		
439	**CL04041023, (dated 29.01.2016 initial), Amendment 2, dated 23.11.2016**	2015-005307-83	olokizumab (CDP6038, L04041)	Humira® (adalimumab)	Da	*Afecţiuni ale sistemului musculo-scheletic*	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	R-Pharm, Moscova	*internaţional*	A Randomized, Double-Blind, Parallel-Group, Placebo- and Active-Controlled, Multicenter Phase III Study of the Efficacy and Safety of Olokizumab in Subjects with Moderately to Severely Active Rheumatoid Arthritis Inadequately Controlled by Methotrexate Therapy	III	70		**28.03.2017**	**22.09.2016**			
440	**R475-PN-1523, Amendment 0.1VHP, dated 18.02.2016 VHP2015187**	2015-003783-36	fasinumab (REGN475)	Nu	Da	*Afecţiuni ale sistemului musculo-scheletic*	ICON Clinical Research SRL Alin Bălăiţău E-mail: ICONRomania@iconplc.com	Regeneron Pharmaceuticals, Inc.	*internaţional*	A Phase 3 Randomized, Double-Blind, Multi-Dose, Placebo-Controlled Study to Evaluate the Long-Term Safety and the Efficacy of Fasinumab in Patients with Pain Due to Osteoarthritis of the Knee or Hip	III	482		**05.05.2016**		**09.09.2016**		
441	**M13-549, Amendment 2, dated 01.04.2016 VHP2016007**	2015-003332-13	ABT-494	Nu	Da	*Afecţiuni ale sistemului imunitar*	SC Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	*internaţional*	A Phase 3, Randomized, Double-Blind Study Comparing ABT-494 to Placebo in Subjects with Moderately to Severely Active Rheumatoid Arthritis Who are on a Stable Dose of Conventional Synthetic Disease-Modifying Anti- Rheumatic Drugs (csDMARDs) and Have an Inadequate Response to csDMARDs	III	9		**18.05.2016**	**15.11.2016**	**21.12.2016**		
442	**M14-465, Amendment 3, dated 01.04.2016 VHP2016008**	2015-003333-95	ABT-494	Humira® (adalimumab)	Da	*Afecţiuni ale sistemului imunitar*	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	*internaţional*	A Phase 3, Randomized, Double-Blind Study Comparing ABT-494 to Placebo and to Adalimumab in Subjects with Moderately to Severely Active Rheumatoid Arthritis Who are on a Stable Background of Methotrexate (MTX) and Who Have an Inadequate Response to MTX (MTX-IR)	III	30		**22.07.2016**		**01.02.2017**		

443	**ZTI-01-200, version 3.0, dated 29.03.2016**	2015-003372-73	fosfocina (ZTI-01, fosfomycin)	Piperacillin/Tazobactam® (piperacillin+tazobactam)	Nu	Infecţii bacteriene şi micoze	August Research SRL Andreea Cătălina Stoenescu E-mail: cstoenescu@augustresearch.com	Zavante Therapeutics, Inc.	internaţional	A Multi-center, Randomized, Double-blind, Comparative Study to Evaluate the Safety and Efficacy of ZTI-01 Versus Piperacillin/Tazobactam in the Treatment of Complicated Urinary Tract Infections, Including Acute Pyelonephritis, in Hospitalized Adults	II/III	54		**18.11.2016**	**22.09.2016**	**07.12.2016**	**21.01.2017**	
444	**SP1042, Amendment 1, dated 01.07.2015**	2015-001549-96	Vimpat® (lacosamide, SPM927)	Nu	Nu	Afecţiuni ale sistemului nervos	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	UCB BioPharma SPRL	internaţional	A multicenter, open-label, follow-up study to assess the long-term use of Lacosamide (flexible dose from 200 to 600 mg/day) used as monotherapy in subjects who completed SP0994 and received Lacosamide monotherapy treatment	III	21		**04.10.2016**		**31.10.2016**		
445	**D6571C00001, version 3.0, dated 21.03.2016**	2015-005444-33	Duaklir Genuair® (aclidinium bromide/formoterol fumarate, LAS40464) Eklira Genuair® (aclidinium bromide, LAS34273) formoterol fumarate	Spiriva Handihaler® (tiotropium bromide)	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Sinziana Oana E-mail: sinziana.oana@parexel.com	AstraZeneca AB	internaţional	A 24 week treatment, multicenter, randomized, double blinded, double dummy, parallel-group, clinical trial evaluating the efficacy and safety of aclidinium bromide 400 µg/formoterol fumarate 12 µg fixed-dose combination BID compared with each monotherapy (aclidinium bromide 400 µg BID and formoterol fumarate 12 µg BID) and tiotropium 18 µg QD when administered to patients with stable chronic obstructive pulmonary disease	III	36		**25.10.2016**			**05.12.2016**	
446	**MK-0431-846, version 01, dated 10.03.2016**	2015-004990-34	Januvia® (sitagliptin, MK-0431)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.	internaţional	A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Study the Efficacy and Safety of the Continuation of Sitagliptin Compared with the Withdrawal of Sitagliptin During Initiation and Titration of Insulin Glargine (LANTUS®) in Subjects with Type 2 Diabetes Mellitus	III	30		**19.09.2016**	**08.08.2016**	**14.10.2016**		
447	**LPS14584, version 1, dated 18.12.2015**	2015-005101-36	Toujeo® (insulin glargine, HOE901-U300)	Tresiba® (insulin degludec)	Nu	Afecţiuni nutriţionale şi metabolice	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	sanofi-aventis Groupe	internaţional	A 24-Week, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of Toujeo® and Tresiba® in Insulin-Naive Patients with Type 2 Diabetes Mellitus Not Adequately Controlled with Oral Antihyperglycemic Drug(s) ± GLP-1 Receptor Agonist	IV	130		**07.09.2016**		**30.09.2016**		
448	**VK5211-201, (version 3.1/Am 2.1, dated 25.02.2016 initial), version 3.2 Romania, Amendment 2.2, dated 03.10.2016**	2016-000377-20	VK5211	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Argint International Clinical Research & Development Services SRL Irina Baros-Gheorghiade E-mail: irina.baros@argintinternational.com	Viking Therapeutics, Inc.	internaţional	A Phase II, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi-Center Study to Explore the Efficacy, Safety and Tolerability of VK5211 in Subjects with Acute Hip Fracture	II	20		**14.10.2016**	**02.08.2016**	**18.11.2016**		
449	**LT1580-301, version 1.1, dated 26.02.2016 VHP2016003**	2015-005405-36	ciclosporin (T1580)	Nu	Da	Afecţiuni oculare	Syncro Clinical Research SRL Gabor Brok E-mail: gbrok@syncrotrial.ro	Laboratoires Théa	internaţional	Efficacy and Safety Assessment of T1580 versus Vehicle in Dry Eye Disease Treatment	III	10		**04.05.2016**	**23.06.2016**	**10.03.2017**		
450	**AKB-6548-CI-0015, version 2.0 Amendment 1, dated 17.03.2016 VHP2016001**	2015-004774-14	vadadustat (AKB-6548)	Aranesp® (darbepoetin alfa)	Nu	Afecţiuni limfatice şi ale sângelui	Voisin Consulting Delphine Decker E-mail: decker@voisinconsulting.com	Akebia Therapeutics, Inc.	internaţional	Phase 3, randomized, open-label, active-controlled study evaluating the efficacy and safety of oral vadadustat for the maintenance treatment of anemia in subjects with non-dialysis-dependent chronic kidney disease (NDD-CKD) (PRO2TECT-CONVERSION)	III	25		**24.05.2016**		**25.10.2016**		
451	**LTS12551, version 1, dated 04.06.2015**	2013-003856-19	dupilumab (SAR231893)	Nu	Nu	Afecţiuni ale tractului respirator	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	Sanofi-aventis recherche et développement	internaţional	Open-label Extension Study to Evaluate the Long-term Safety and Tolerability of Dupilumab in Patients With Asthma Who Participated in a Previous Dupilumab Asthma Clinical Study	II/III	11		**20.12.2016**	**21.12.2016**	**12.01.2017**		
452	**PA-CL-PED-01, version 2.0, dated 22.09.2015**	2015-004155-43	Velphoro® (sucroferric oxyhydroxide)	Phoslyra® (calcium acetate)	Nu	Fenomene metabolice	Covance Clinical & Periapproval Services Limited Loredana Rădulescu E-mail: loredana.radulescu@covance.com	Vifor Fresenius Medical Care Renal Pharma France	internaţional	An Open-label, Randomised, Active-controlled, Parallel Group, Multicentre, Phase 3 Study to Investigate the Safety and Efficacy of PA21 (Velphoro®) and Calcium Acetate (Phoslyra®) in Paediatric and Adolescent CKD Patients with Hyperphosphataemia	III	16		**07.02.2017**	**13.10.2016**	**04.04.2017**		
453	**Vedolizumab-4013, version Original, dated 17.03.2016**	2016-000678-40	Entyvio® (vedolizumab, MLN002)	Nu	Nu	Afecţiuni ale sistemului digestiv	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppd.com	Takeda Development Centre Europe Limited, UK	internaţional	Entyvio (Vedolizumab IV) Extended Access Program in Ulcerative Colitis and Crohn's Disease	IV	3		**16.11.2016**				
454	**RGH-MD-53, Amendment 2, dated 17.02.2016**	2016-000756-98	Vraylar® (cariprazine, RGH-188)	Nu	Da	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Octavia Zamfir E-mail: octavia.zamfir@quintiles.com	Forest Laboratories LLC, an Allergan Affiliate, SUA	internaţional	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Fixed-Dose Clinical Trial Evaluating the Efficacy, Safety and Tolerability of Cariprazine in Patients with Bipolar I Depression	III	67		**11.04.2017**		**19.06.2017**		
455	**54179060LYM3003, (version Initial, dated 12.02.2016 initial), Amendment 1, dated 21.06.2016**	2016-000259-28	ibrutinib (JNJ-54179060)	Nu	Nu	Afecţiuni oncologice	SC Johnson&Johnson Romania SRL Madalina Rotariu E-mail:mrotariu@its.jnj.com	Janssen-Cilag International NV, Belgia	internaţional	A Randomized, Open-label, Safety and Efficacy Study of Ibrutinib in Pediatric and Young Adult Patients With Relapsed or Refractory Mature B-cell non-Hodgkin Lymphoma	III	8		**07.02.2017**	**29.09.2016**	**23.05.2017**		

456	**D1001066, version 1.0, dated 24.03.2016**	2016-000060-42	Latuda® (lurasidone, SM-13496)	Nu	Da	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Sunovion Pharmaceuticals Inc., USA	internaţional	A 6-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Lurasidone (SM-13496) in Acutely Psychotic Subjects with Schizophrenia	III	66		**18.01.2017**		**28.04.2017**		
457	**D1001067, version 1.0, dated 24.03.2016**	2016-000061-23	Latuda® (lurasidone, SM-13496)	Nu	Nu	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Sunovion Pharmaceuticals Inc., USA	internaţional	A 12-Week, Open-Label Extension Study of Lurasidone (SM-13496) in Subjects with Schizophrenia	III	40		**10.03.2017**		**27.06.2017**		
458	**MO29594, version 2, dated 21.01.2016**	2014-005491-28	Avastin® (bevacizumab, RO4876646/F02) carboplatin paclitaxel	Nu	Da	Afecţiuni oncologice	Roche Romania SRL Laura Colpcaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	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	II	5		**05.09.2016**	**10.08.2016**	**01.10.2016**		
459	**GFT505-315-1, version Final 1.0, dated 15.01.2016**	2015-005385-38	elafibranor (GFT505)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Covance Clinical & Periapproval Services Limited Ioana Stupar E-mail: Ioana.Stupar@covance.com	Genfit SA	internaţional	A Multicentre, Randomized, Double-Blind, Placebo-Controlled Phase III Study to Evaluate the Efficacy and Safety of Elafibranor in Patients with Non-Alcoholic Steatohepatitis (NASH) and fibrosis	III	50		**28.10.2016**	**22.09.2016**	**31.01.2017**		
460	**FKB238-002, version 03, dated 20.04.2016**	2015-004104-33	FKB238 (bevacizumab)	Avastin® (bevacizumab)	Nu	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Irina Moldoveanu E-mail: Irina.Moldoveanu@parexel.com	Centus Biotherapeutics Limited	internaţional	A Randomised, Parallel, Double Blinded Study to Compare the Efficacy and Safety of FKB238 to Avastin® In 1st Line Treatment for Patients with Advanced/Recurrent Non Squamous Non-Small Cell Lung Cancer in Combination of Paclitaxel and Carboplatin	III	24		**20.12.2016**		**27.01.2017**		
461	**PM1183-C-003-14, version 2.0, dated 18.03.2016**	2015-001641-89	lurbinectedin (PM01183)	Doxorubicin® (doxorubicin) Topotecan® (topotecan) Cyclophosphamid® (cyclophosphamide) Vincristine® (vincristine)	Nu	Afecţiuni oncologice	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Pharma Mar S.A	internaţional	Phase III Randomized Clinical Trial of Lurbinectedin (PM01183)/Doxorubicin (DOX) versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as Treatment in Patients with Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line (ATLANTIS Trial)	III	25		**25.01.2017**	**31.10.2016**	**22.02.2017**		
462	**M15-574, Amendment 1, dated 05.05.2016 VHP2016031**	2015-005161-23	Humira® (adalimumab)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 4, Double-Blind, Randomized, Placebo-Controlled Multicenter Study to Assess the Safety and Efficacy of Adalimumab Used in Conjunction with Surgery in Subjects with Moderate to Severe Hidradenitis Suppurativa	IV	10		**22.09.2016**				
463	**MC-FludT.16/NM, version 1.0 (RO), dated 20.04.2016**	2013-005508-33	treosulfan (Ovastat®)	Busilvex® (busulfan)	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	medac GmbH	internaţional	Clinical phase II trial to compare Treosulfan-based conditioning therapy with Busulfan-based conditioning prior to allogeneic haematopoietic stem cell transplantation (HSCT) in paediatric patients with non-malignant diseases	II	5		**18.05.2017**				
464	**ONS-3010-002, version 1.1, dated 14.04.2016 VHP2016035**	2015-004614-26	adalimumab (ONS-3010)	Humira® (adalimumab)	Nu	Afecţiuni ale pielii şi ţesutului conjunctiv	inVentiv Health Clinical Romania SRL Monica Angelescu E-mail: monica.angelescu@inventivhealth.com	Oncobiologics Limited	internaţional	A Randomized, Double-Blind, Multicenter, Equivalence Study of ONS-3010 and Humira® for the Treatment of Patients with Moderate to Severe Plaque Psoriasis	III	9		**21.06.2016**				
465	**M14-327, Amendment 1, dated 13.06.2016 VHP2016021**	2015-003759-23	ABT-494	Nu	Nu	Afecţiuni ale sistemului digestiv	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 2, Multicenter, Open-Label Extension (OLE) Study to Observe the Long-Term Efficacy, Safety, and Tolerability of Repeated Administration of ABT-494 in Subjects with Crohn's Disease	II	10		**22.09.2016**				
466	**205543, version Final, dated 25.04.2016**	2016-000459-28	Tivicay® (dolutegravir, GSK1349572) Epivir® (lamivudine, GR109714)	Truvada® (emtricitabine+tenofovir disoproxil)	Nu	Afecţiuni virale	PPD Romania SRL Ana-Maria Tanase E-mail: Ana.Tanase@ppdi.com	ViiV Healthcare UK Limited	internaţional	A Phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment-naïve adults	III	13		**07.12.2016**	**26.09.2016**	**28.12.2016**		
467	**204861, version Final, dated 25.04.2016**	2015-004418-95	Tivicay® (dolutegravir, GSK1349572) Epivir® (lamivudine, GR109714)	Truvada® (emtricitabine+tenofovir disoproxil)	Nu	Afecţiuni virale	PPD Romania SRL Ana-Maria Tanase E-mail: Ana.Tanase@ppdi.com	ViiV Healthcare UK Limited	internaţional	A Phase III, randomised, double-blind, multicentre, parallel-group, non-inferiority study evaluating the efficacy, safety, and tolerability of dolutegravir plus lamivudine compared to dolutegravir plus tenofovir/emtricitabine in HIV-1-infected treatment-naïve adults	III	14		**07.12.2016**	**26.09.2016**	**19.01.2017**		
468	**CA209-577, version Initial, dated 06.01.2016**	2015-005556-10	nivolumab (BMS-936558)	Nu	Da	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Randomized, Multicenter, Double Blind, Phase III Study of Adjuvant Nivolumab or Placebo in Subjects with Resected Esophageal, or Gastroesophageal Junction Cancer	III	30		**15.11.2016**	**18.08.2016**	**21.11.2016**		

469	**CRFB002H2301E1, version 00, dated 11.12.2015**	2014-004048-36	Lucentis® (ranibizumab, RFB002)	Nu	Nu	Afecţiuni oftalmice	PAREXEL International Romania s.r.l. Andreea Raluca Ghinea E-mail: andreea-raluca.ghinea@parexel.com	Novartis Pharma Services AG, Elveţia	internaţional	RAINBOW extension study: an extension study to evaluate the long term efficacy and safety of RAnibizumab compared with laser therapy for the treatment of INfants BOrn prematurely With retinopathy of prematurity	III	9		**19.01.2017**		**31.05.2017**		
470	**MYL-1402O-3001, version 1.0, datata 09.03.2016**	2015-005141-32	MYL-1402O (bevacizumab biosimilar)	Avastin® (bevacizumab)	Nu	Afecţiuni oncologice	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppdi.com	Mylan GmbH	internaţional	Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the Firstline Treatment of Patients with Stage IV Non-Squamous Non-Small Cell Lung Cancer	III	18		**13.02.2017**				
471	**SL0023, Final, dated 12.04.2016**	2015-004457-40	dapirolizumab pegol (DZP, CDP7657)	Nu	Da	Afecţiuni ale sistemului imunitar	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	UCB Biopharma SPRL, Belgia	internaţional	A Multi-Center, Randomized, Double Blind, Placebo-Controlled, Parallel Group, Dose Ranging Study Followed By An Observational Period To Evaluate The Efficacy And Safety Of Dapirolizumab Pegol In Subjects With Moderately To Severely Active Systemic Lupus Erythematosus	II	30		**25.01.2017**		**01.03.2017**		
472	**M14-361, (Amendment 3, dated 18.12.2015 initial), Amendment 5, dated 22.11.2016, Incorporating Administrative Changes 1, dated 17.07.2015, Administrative Changes 2, dated 28.07.2016**	2014-001764-35	veliparib (ABT-888)	Nu	Da	Afecţiuni oncologice	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 1 Dose Escalation and Phase 2 Randomized Double-Blind Study of Veliparib in Combination with Carboplatin and Etoposide as a Therapy of Treatment-Naïve Extensive Stage Disease Small Cell Lung Cancer	II	15		**18.05.2017**				
473	**M15-555, Amendment 2.02, dated 27.05.2016 VHP2016040**	2015-003376-75	ABT-494 Methotrexate® (methotrexate)	Nu	Nu	Afecţiuni ale sistemului imunitar	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 3, Randomized, Double-Blind Study Comparing ABT-494 Monotherapy to Methotrexate (MTX) in Subjects with Moderately to Severely Active Rheumatoid Arthritis with Inadequate Response to MTX	III	6		**27.06.2016**				
474	**M13-545, Amendment 3, dated 31.05.2016 VHP2016039**	2015-003334-27	ABT-494 Methotrexate® (methotrexate)	Nu	Da	Afecţiuni ale sistemului imunitar	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 3, Randomized, Double-Blind Study Comparing ABT-494 Once Daily Monotherapy to Methotrexate (MTX) Monotherapy in MTX-Naïve Subjects with Moderately to Severely Active Rheumatoid Arthritis	III	24		**26.09.2016**				
475	**EFC13794, version 1, dated 11.02.2016 VHP2016057**	2014-004850-32	HOE901/AVE0010 (lixisenatide + insulin glargine)	Victoza® (liraglutide) Byetta® (exenatide) Bydureon® (exenatide)	Nu	Afecţiuni nutriţionale şi metabolice	Sanofi Romania SRL Alexandra Voicu E-mail: Alexandra.VoicuConstantinMF@sanofi.com	sanofi-aventis recherche & développement	internaţional	A 26-week randomized, open-label, active controlled, parallel-group, study assessing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination in adults with Type 2 Diabetes inadequately controlled on GLP-1 receptor agonist and metformin (alone or with pioglitazone and/or SGLT2 inhibitors), followed by a fixed ratio combination single-arm 26-week extension period	III	35		**08.07.2016**	**07.07.2016**	**09.08.2016**		
476	**CAIN457F3302, version 00, dated 15.03.2016**	2016-000814-31	Cosentyx® (secukinumab, AIN457)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	PAREXEL International Romania s.r.l. Dominica Tone E-mail: europe.cta@novartis.com	Novartis Pharma Services AG	internaţional	MAXIMISE (Managing AXIal Manifestations in Psoriatic Arthritis with SEcukinumab), a randomized, double-blind, placebo-controlled, multicenter, 52 week study to assess the efficacy and safety of secukinumab 150 mg or 300 mg s.c. in patients with active psoriatic arthritis and axial skeleton involvement who have inadequate response to non steroidal anti-inflammatory drugs (NSAIDs)	III	10		**19.05.2017**		**21.06.2017**		
477	**MS200527-0081, version 2.0, dated 11.05.2016 VHP2016053**	2016-000064-42	M2951	Nu	Da	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Merck KGaA	internaţional	Phase IIa Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of M2951 in Subjects with Rheumatoid Arthritis on Stable Methotrexate Therapy	II	8						
478	**NAB-BC-3781-3102, version 3.0, dated 17.03.2016**	2015-004782-92	lefamulin (BC-3781)	Avelox® (moxifloxacin)	Da	Afecţiuni ale tractului respirator	Covance Clinical & Periapproval Services Limited Ilinca Nicolescu E-mail: Ilinca.Nicolescu@covance.com	Nabriva Therapeutics AG, Austria	internaţional	A Phase 3, Randomized, Double-Blind, Double-Dummy Study to Compare the Efficacy and Safety of Oral Lefamulin (BC-3781) Versus Oral Moxifloxacin in Adults With Community-Acquired Bacterial Pneumonia	III	50		**28.12.2016**	**17.11.2016**	**14.02.2017**		
479	**UC0011, (Amendment 1, dated 10.05.2016 initial), Amendment 2, dated 14.10.2016**	2016-000420-26	bimekizumab (UCB4940)	Nu	Da	Afecţiuni ale sistemului digestiv	Arensia Exploratory Medicine SRL Camelia Nita E-mail: camelia.nita@arensia-em.com	UCB Biopharma SPRL	internaţional	A multicenter, subject-blind, investigator-blind, randomized, placebo-controlled study evaluating the efficacy, safety, tolerability, and pharmacokinetics of an IV loading dose followed by sc administration of bimekizumab (UBC4940) in subjects with moderate to severe active ulcerative colitis	II	45		**06.03.2017**	**07.11.2016**			
480	**WO30070, version 2, dated 27.05.2016 VHP2016046**	2016-000250-35	atezolizumab (RO5541267, MPDL3280A) Carboplatin® (carboplatin) Gemcitabin® (gemcitabine)	Carboplatin® (carboplatin) Gemcitabin® (gemcitabine)	Da	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd	internaţional	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	III	10		**10.08.2016**		**08.11.2016**		
481	**AB14005, version 3.1, dated 06.04.2016**	2015-000897-36	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni oncologice	HT Research RO SRL Marisa Manzala E-mail: manzala@hungarotrial.com	AB Science	internaţional	A prospective, multicentre, double-blind, randomized, placebo-controlled, phase 3 study to evaluate efficacy and safety of masitinib with irinotecan in patients with advanced-stage esophagogastric adenocarcinoma who have relapsed after first-line chemotherapy	III	50						

482	**FRAG-A001-201 (A6301094), version Final Amendment 8, dated 24.03.2016 + Administrative changes Letter, 09 Aprilie 2016**	2016-000394-21	Fragmin® (dalteparin sodium, PN180524)	Nu	Nu	Afecţiuni cardiovasculare	InVentiv Health Clinical Romania SRL Monica Angelescu E-mail: monica.angelescu@inventivhealth.com	Pfizer Inc., SUA	internaţional	A Three Month Prospective Open Label Study of Therapy with Fragmin® (Dalteparin Sodium Injection) in Children with Venous Thromboembolism with or Without Malignancies	II	3		**22.03.2017**	**15.12.2016**			
483	**204957, (version 01, dated 02.06.2016 initial), Amendment 02, dated 08.12.2016**	2015-005800-27	GSK3117391	Nu	Da	Afecţiuni ale sistemului imunitar	GlaxoSmithKline (GSK) Romania SRL Veronica Barbulescu E-mail: veronica.x.barbulescu@gsk.com	GlaxoSmithKline Research & Development Ltd., UK	internaţional	A randomised, multi-center, double blind (sponsor open), placebo-controlled study to assess the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of GSK3117391 in subjects with severe, active rheumatoid arthritis	II	4		**16.01.2017**	**10.10.2016**	**15.02.2017**		
484	**TST-EFS-04-MPP/16, version Final 02, dated 02.06.2016 + Protocol Amendment No. 2, dated 22.02.2017**	2016-001492-73	Tescum® gel (testosterone)	Nu	Nu	Afecţiuni hormonale	3S-Pharmacological Consultation & Res. SRL Simona Rizea Savu E-mail: dreispharma@aol.com	M et P Pharma AG, Elveţia	internaţional	Efficacy And Safety Of Two- Or Three-Times Daily Intranasal Administration Of Testosterone Gel (Tescum) In Adult Hypogonadal Male Patients, Divided In 2 Cohorts (Cohort 1 – Efficacy And Long Term Safety Assessment, Cohort 2 – Long Term Safety Assessment	III	60		**06.03.2017**	**10.10.2016**	**18.07.2017**		
485	**1517-CL-0610, (version 3.0, dated 31.03.2016 initial), Version 3.1 [RO] Incorporating Country-Specific Non-Substantial Amendment 2, dated 05.04.2017**	2013-000951-42	roxadustat (FG-4592, ASP1517)	Aranesp® (darbepoetin alfa)	Nu	Afecţiuni limfatice şi ale sângelui	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@iNCResearch.com	Astellas Pharma Europe B.V., Olanda	internaţional	A Phase 3, Randomized, Open-Label, Active-Controlled Study to Evaluate the Efficacy and Safety of Roxadustat in the Treatment of Anemia in Chronic Kidney Disease Patients Not on Dialysis	III	150		**20.04.2017**		**25.05.2017**		
486	**MC-TER.2/SSc, version 1.2, dated 08.06.2016 VHP2016055**	2015-002586-39	terguride hydrogenmaleate	Nu	Da	Afecţiuni ale sistemului imunitar	PPD Romania SRL Ana Andreea Drăghici E-mail: ana.draghici@ppdi.com	medac GmbH	internaţional	Randomized, Multicenter, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Terguride Plus Symptomatic Therapy in Subjects With Diffuse Cutaneous Systemic Sclerosis	III	30		**29.07.2016**				**03.03.2017**
487	**TP-434-025, version 1.0, dated 31.05.2016**	2016-002208-21	eravacycline (TP-434)	meropenem	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Tetraphase Pharmaceuticals, Inc.	internaţional	A Phase 3, Randomized, Double-Blind, Double-Dummy, Multicenter, Prospective Study to Assess the Efficacy and Safety of Eravacycline Compared with Meropenem in Complicated Intra-abdominal Infections	III	91		**09.02.2017**	**03.10.2016**	**21.02.2017**	**19.05.2017**	
488	**16159B, version 1.0, dated 24.05.2016**	2015-003284-11	AF35700	Nu	Nu	Afecţiuni ale sistemului nervos	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@iNCResearch.com	H. Lundbeck A/S, Danemarca	internaţional	Interventional, open-label, flexible-dose, long-term safety study of Lu AF35700 in adult patients with schizophrenia	III	30		**04.04.2017**				
489	**AQX-1125-301, (version 2.0 Final, dated 15.06.2016 initial), (version 3.0 (Amendment 2), dated 19.10.2016), version 4.0, dated 04.04.2017**	2016-000906-12	AQX-1125	Nu	Da	Afecţiuni ale sistemului renal	ICON Clinical Research SRL Alin Bălălău E-mail: iconromania@iconplc.com	Aquinox Pharmaceuticals (Canada) Inc.	internaţional	The LEADERSHIP 301 Trial: A 12-Week, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, 3-Arm, Parallel-Group, Phase 3 Trial to Evaluate the Efficacy and Safety of 2 Doses of AQX-1125 Targeting the SHP1 Pathway in Subjects with Interstitial Cystitis/Bladder Pain Syndrome Followed by an Extension Period	III	29		**05.05.2017**				
490	**ACT14604, version 1, dated 09.06.2016**	2016-001028-80	SAR156597	Nu	Da	Afecţiuni ale sistemului imunitar	Sanofi Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com	sanofi-aventis recherche & développement	internaţional	Efficacy and safety of SAR156597 in the treatment of diffuse cutaneous Systemic Sclerosis (dcSSc): A randomized, double-blind, placebo-controlled, 24-week, proof of concept study	II	10		**05.05.2017**	**05.12.2016**	**12.06.2017**		
491	**205715, version 01, dated 09.06.2016**	2016-001304-37	fluticasone furoate/umeclidinium bromide/vilanterol trifenatate (GW685698/GSK573719/ GW642444)	Relvar Ellipta® (fluticasone furoate/vilanterol trifenatate, GW685698/GW642444)	Nu	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) Romania SRL Ana Magherusan E-mail: ana.l.magherusan@gsk.com	GlaxoSmithKline Research & Development Limited	internaţional	A Phase III, randomized, double-blind, active controlled, parallel group study, comparing the efficacy, safety and tolerability of the fixed dose combination FF/UMEC/VI with the fixed dose dual combination of FF/VI, administered once-daily via a dry powder inhaler in subjects with inadequately controlled asthma	III	150		**20.12.2016**	**13.10.2016**	**29.12.2016**		
492	**B9991001, Amendment 2, dated 24.03.2016**	2015-003262-86	avelumab (MSB0010718C)	Nu	Nu	Afecţiuni oncologice	PPD Romania SRL Ana Andreea Drăghici E-mail: Ana.Draghici@ppdi.com	Pfizer Inc.	internaţional	A Phase 3, 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 (Javelin Bladder 100)	III	10		**16.05.2017**				
493	**NC-6004-008, (version 1.0, dated 11.12.2015 initial), (Amendment 2, Version 3.0, dated 09 December 2016), version 4.0 Amendment 3, dated 13 March 2017**	2016-000866-44	nanoparticle cisplatin (NC-6004) Erbitux® (cetuximab) Fluorouracil® (fluorouracil sodium)	Nu	Nu	Afecţiuni oncologice	PPD Romania SRL Ana-Maria Tănase E-mail: Ana.Tanase@ppdi.com	NanoCarrier Co, Ltd.	internaţional	Phase I/II Clinical Trial of NC-6004 in Combination with 5-FU and Cetuximab as First-line Treatment in Patients with Recurrent or Metastatic Squamous Cell Carcinoma of The Head and Neck	II	13		**14.07.2017**				
494	**AGB002, version 1.3, dated 03.06.2016**	2016-001966-27	SAIT101 (rituximab biosimilar)	MabTheral® (rituximab)	Nu	Afecţiuni limfatice şi ale sângelui	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Archigen Biotech Limited	internaţional	A Randomized, Double-blind, Multi-center, Multi-national Trial to Evaluate the Efficacy, Safety, and Immunogenicity of SAIT101 Versus Rituximab as a First-line Immunotherapy Treatment in Patients with Low Tumor Burden Follicular Lymphoma	III	8		**31.05.2017**	**08.12.2016**			

495	**LUPIL-2, version 1.1, dated 28.06.2016 VHP2016058**	2016-000488-17	ILT-101 (aldesleukin)	Nu	Da	Afecţiuni ale sistemului imunitar	Orion Clinical Services Limited Anisa Abbasi E-mail: anisa.abbasi@orioncro.com	ILTOO PHARMA, Franţa	internaţional	A Phase II, multi-centre, randomized, double blind, placebo-controlled study to evaluate the efficacy, safety and pharmacokinetics of ILT-101 in patients with active moderate to severe systemic lupus erythematosus (SLE)	II	15		**14.10.2016**	**10.11.2016**	**03.03.2017**		
496	**CV185-316, version Revised Protocol No.: 02a Incorporates amendment(s): 03, dated 16.05.2016**	2014-002004-24	Eliquis® (apixaban, BMS-562247-01)	acetylsalicylic acid (aspirin) Aldocumarl® (warfarin sodium)	Nu	Afecţiuni cardiovasculare	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation	internaţional	An Open-label, 2 x 2 Factorial, Randomized Controlled, Clinical Trial to Evaluate the Safety of Apixaban vs. Vitamin K Antagonist and Aspirin vs. Aspirin Placebo in Patients with Atrial Fibrillation and Acute Coronary Syndrome or Percutaneous Coronary Intervention. (Augustus)	III	300		**27.03.2017**				
497	**64304500CRD2001, (Amendment 1, dated 14.06.2016 initial), Amendment 2, dated 09.11.2016**	2016-000634-21	JNJ-64304500	Stelara® (ustekinumab)	Da	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Florentina Alexandru Berlic E-mail: florentina.alexandru-berlic@parexel.com	Janssen-Cilag International NV	internaţional	A Phase 2b, Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Protocol to Evaluate the Safety and Efficacy of JNJ-64304500 in Subjects with Moderately to Severely Active Crohn's Disease	II	22		**24.07.2017**				
498	**SEP361-202, version 2.00, dated 23.06.2016**	2016-001556-21	SEP-363856	Nu	Nu	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Sunovion Pharmaceuticals Inc.	internaţional	A 26-Week Open-label Safety and Tolerability Extension Study of SEP-363856 in Adult Subjects with Schizophrenia	II	35						
499	**SEP361-201, (version 2.00, dated 23.06.2016 initial), version 3.00, dated 22.03.2017**	2016-001555-41	SEP-363856	Nu	Da	Afecţiuni ale sistemului nervos	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Sunovion Pharmaceuticals Inc., USA	internaţional	A 4-Week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexibly-dosed, Multicenter Study to Evaluate the Efficacy and Safety of SEP-363856 in Acutely Psychotic Adult Subjects With Schizophrenia	II	42		**20.04.2017**				
500	**D3461C00009, version 2.0, dated 06.05.2016**	2016-000625-39	anifrolumab (MEDI-546)	Nu	Da	Afecţiuni ale sistemului imunitar	Pharmaceutical Research Associates Romania SRL Ruxandra Crisan E-mail: crisanruxandra@prahs.com	AstraZeneca AB	internaţional	A Multicentre, Randomised, Double-blind, Placebo-Controlled Phase 3 Extension Study to Characterise the Long-term Safety and Tolerability of Anifrolumab in Adult Subjects with Active Systemic Lupus Erythematosus	III	7		**30.05.2017**	**02.02.2017**	**26.07.2017**		
501	**W-4873-201, (version 1.0, dated 10.05.2016 initial), version 1.1, dated 29.11.2016**	2016-001246-26	nafithromycin (WCK 4873)	Avelox® (moxifloxacin)	Da	Afecţiuni ale tractului respirator	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Wockhardt Bio AG	internaţional	A Phase II, Randomized, Double-Blind, Multicenter, Comparative Study to Determine the Safety, Tolerability, Pharmacokinetics and Efficacy of Oral Nafithromycin Versus Oral Moxifloxacin in the Treatment of Community-Acquired Bacterial Pneumonia (CABP) in Adults	II	45		**07.12.2016**	**03.11.2016**	**21.01.2017**		
502	**1014802-204, version 3, dated 14.07.2016**	2015-004796-68	BIIB074	Nu	Nu	Afecţiuni ale sistemului nervos	Pharm-Olam International (UK) Ltd.) Ramona Nicolescu E-mail: ramona.nicolescu@pharm-olam.com	Convergence Pharmaceuticals Ltd.	internaţional	An Uncontrolled, Open-Label Extension Study to Evaluate the Long Term Safety, Tolerability, and Maintenance of Effect of BIIB074 in Subjects With Neuropathic Pain From Lumbosacral Radiculopathy	II	50		**15.06.2017**	**06.03.2017**			
503	**CSOM230B2412, version 01, dated 11.03.2016**	2013-000267-84	Signifor® (pasireotide, SOM230)	Nu	Nu	Afecţiuni hormonale	PAREXEL International Romania s.r.l. Andreea Fischea E-mail: europe.cta@novartis.com	Novartis Pharma Services AG, Elveţia	internaţional	An open label, multicenter pasireotide roll over protocol for patients who have completed a previous Novartis sponsored pasireotide study and are judged by the investigator to benefit from continued pasireotide treatment	IV	15		**28.12.2016**		**25.01.2017**		
504	**COMB157G2301, version 00, dated 07.04.2016**	2015-005418-31	Arzerra® (ofatumumab, OMB157)	Aubagio® (teriflunomide)	Da	Afecţiuni ale sistemului nervos	PAREXEL International Romania s.r.l. Mihaela Buhaciuc E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG	internaţional	A randomized, double-blind, double-dummy, parallel-group study comparing the efficacy and safety of ofatumumab versus teriflunomide in patients with relapsing multiple sclerosis	III	12			**04.04.2017**			
505	**HZA114971, (version 00, dated 28.06.2016 initial), Amendment 01, dated 04.11.2016**	2016-002551-22	fluticasone furoate	Nu	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Mihaela Cristina Constantinescu E-mail: Mihaela.Constantinescu@parexel.com	GlaxoSmithKline Research & Development Limited, UK	internaţional	Study HZA114971, A Multicentre Randomised, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effects of a One-Year Regimen of Orally Inhaled Fluticasone Furoate 50 mcg once daily on Growth Velocity in Prepubertal, Paediatric Subjects with Asthma	IV	56						
506	**VUMC-ARC-GLORIA, (version 1.0, dated 19.10.2015 initial), version 2.1, dated 04.02.2016**	2015-002729-21	Prednisolone Labesfalt® (prednisolone)	Nu	Da	Afecţiuni ale sistemului imunitar	SMP Clinical Development Dionisie Czika E-mail: dionisie.czika@smp.ro	VU University Medical Center, Olanda	internaţional	The Glucocorticoid Low-dose Outcome in Rheumatoid Arthritis Study Comparing the cost-effectiveness and safety of additional low-dose glucocorticoid in treatment strategies for elderly patients with rheumatoid arthritis	IV	100		**19.12.2016**	**27.10.2016**			
507	**COMB157G2302, version 00, dated 07.04.2016**	2015-005419-33	Arzerra® (ofatumumab, OMB157)	Aubagio® (teriflunomide)	Da	Afecţiuni ale sistemului nervos	PAREXEL International Romania s.r.l. Mihaela Buhaciuc E-mail: Europe.CTA@Novartis.com	Novartis Pharma AG, Elveţia	internaţional	A randomized, double-blind, double-dummy, parallel-group study comparing the efficacy and safety of ofatumumab versus teriflunomide in patients with relapsing multiple sclerosis	III	12			**04.04.2017**			

508	**CA209-649, (version Original, dated 04.05.2016 initial), revised protocol 02 (incorporating amendment (s) 08, dated 07.12.2016**	2016-001018-76	nivolumab (BMS-936558) ipilimumab (BMS-734016)	oxaliplatin capecitabine folinic acid fluorouracil	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Randomized, Multicenter, Open-Label, Phase 3 Study of Nivolumab plus Ipilimumab or Nivolumab in Combination with Oxaliplatin plus Fluoropyrimidine versus Oxaliplatin plus Fluoropyrimidine in Subjects with Previously Untreated Advanced or Metastatic Gastric or Gastroesophageal Junction Cancer (CheckMate 649: CHECKpoint pathway and nivoluMab clinical Trial Evaluation 649)	III	30		**27.07.2017**	**24.11.2016**			
509	**201023, version 00, dated 12.07.2016**	2016-002512-40	danirixin (GSK1325756) Tamiflu® (oseltamivir phosphate)	Nu	Da	Afecţiuni virale	GlaxoSmithKline (GSK) Romania SRL Madalina Margarit E-mail: madalina.x.margarit@gsk.com	GlaxoSmithKline Research & Development Limited, UK	internaţional	A Phase II, global, randomized study to evaluate the efficacy and safety of Danirixin (GSK1325756) co-administered with a standard-of-care antiviral (oseltamivir), in the treatment of adults hospitalized with influenza	II	60		**15.02.2017**	**19.12.2016**		**20.07.2017**	
510	**FFIS/2015/01/ST, versiunea 2.0, datat 06.02.2016**	2015-005130-22	pravastatin	Nu	Da	Afecţiuni ale sistemului reproducător	Spitalul Clinic Filantropia Anca Maria Panaitescu E-mail: panaitescu.anca@yahoo.com	Fundacion Para La Formacion e Investigation Sanitaria (FFIS), Spania	internaţional	Randomised controlled trial with Pravastatin versus placebo for prevention of Preeclampsia (STATIN)	III	150			**15.09.2016**			
511	**GWEP1447, version 4, dated 26.07.2016**	2015-002939-18	cannabidiol (GWP42003-P) Diacomit® (stiripentol) sodium valproate	Nu	Da	Afecţiuni ale sistemului nervos	GW Research Ltd. Octavian Florin Magazin	GW Research Ltd.	internaţional	A phase 2, double-blind, randomized, placebo-controlled pharmacokinetic trial in two parallel groups to investigate possible drug-drug interactions between stiripentol or valproate and GWP42003-P in patients with epilepsy	II	10			**10.05.2017**			
512	**200622, version 00, dated 29.04.2016**	2014-001232-11	Nucala® (mepolizumab, SB240563)	Nu	Da	Afecţiuni limfatice şi ale sângelui	GlaxoSmithKline (GSK) Romania SRL Mirela Petronela Chiricescu E-mail: mirela.g.chiricescu@gsk.com	GlaxoSmithKline Research & Development Ltd	internaţional	Study 200622: A randomized, double-blind, placebo-controlled study to investigate the efficacy and safety of mepolizumab in the treatment of adolescent and adult subjects with severe hypereosinophilic syndrome	III	5		**24.07.2017**	**12.12.2016**			
513	**I4T-MC-JVCY, version C, dated 27.04.2016**	2014-004824-22	Tarceva® (erlotinib) Cyramza® (ramucirumab)	Nu	Da	Afecţiuni oncologice	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company	internaţional	A Multicenter, Randomized, Double-Blind Study of Erlotinib in Combination with Ramucirumab or Placebo in Previously Untreated Patients with EGFR Mutation-Positive Metastatic Non-Small Cell Lung Cancer	III	12			**19.01.2017**			
514	**DUR001-306, Amendment 3, dated 13.06.2016**	2014-005281-30	Xydalba® (dalbavancin)	oxacillin vancomycin hydrochloride fluctoxacillin clindamycin hydrochloride cefladroxil	Nu	Infecţii bacteriene şi micoze	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@INCResearch.com	Durata Therapeutic International B.V. (an Allergan Affiliate), Olanda	internaţional	A Phase 3, Multicenter, Open-Label, Randomized, Comparator Controlled Trial of the Safety and Efficacy of Dalbavancin versus Active Comparator in Pediatric Subjects with Acute Bacterial Skin and Skin Structure Infections	III	48						
515	**RPC01-3102, version 3.0, dated 07.06.2016**	2015-001600-64	ozanimod (RPC1063)	Nu	Nu	Afecţiuni ale sistemului digestiv	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Celgene International II Sàrl	internaţional	A Phase 3, Multicenter, Open-Label Extension Trial of Oral RPC1063 as Therapy for Moderate to Severe Ulcerative Colitis	III	27						
516	**RPC01-3101, version 2.0, dated 07.06.2016**	2015-000319-41	ozanimod (RPC1063)	Nu	Da	Afecţiuni ale sistemului digestiv	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Celgene International II Sàrl (CIS II)	internaţional	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial of Oral RPC1063 as Induction and Maintenance Therapy for Moderate to Severe Ulcerative Colitis	III	45						
517	**KCT03/2015--DORETA, version RO1.4, dated 21.03.2016**	2015-002875-20	Doretal® (tramadol hydrochloride+paracetamol)	Nu	Nu	Afecţiuni ale sistemului musculo-scheletic	ACT FARMA CRO SRL Silviu Lungu E-mail: silviu@transmedika.ro	KRKA ROMANIA S.R.L.	internaţional	Efficacy and Safety of Prolonged Release (SR) Tramadol Hydrochloride (HCl)/Paracetamol fixed combination and Immediate Release (IR) Tramadol HCl/Paracetamol fixed combination in Patients with Moderate to Severe Acute Low-Back Pain - TreaSuRe	III	70						
518	**GB39242, version 2, dated 31.05.2016 VHP2016092**	2016-001549-13	MSTT1041A (Ro 718-7807/F01, anti-ST2 (IgG2) human monoclonal antibody)	Nu	Da	Afecţiuni ale tractului respirator	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	Genentech, Inc.	internaţional	A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Dose-Ranging Study To Assess The Efficacy And Safety Of MSTT1041A In Patients With Uncontrolled Severe Asthma	II	10		**26.09.2016**		**04.01.2017**		
519	**I4X-MC-JFDA, Amendment (a), dated 28.06.2016 VHP2016096**	2016-002041-31	Portrazza® (necitumumab) Gemzar® (gemcitabine) Carboplatin® (carboplatin)	Nu	Nu	Afecţiuni oncologice	Eli Lilly Romania SRL Luminita Butnaru E-mail: butnaru_luminita@lilly.com	Eli Lilly and Company	internaţional	A Single-Arm, Multicenter, Phase 2 Study of Gemcitabine-Carboplatin Chemotherapy Plus Necitumumab in the First-Line Treatment of Patients with Locally Advanced or Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)	II	8		**14.10.2016**	**20.10.2016**		**11.11.2016**	
520	**DU176b-D-U312, version 1.0, dated 21.04.2016**	2016-000991-49	Lixiana® (edoxaban, DU176B) edoxaban (DU176B)	standard of care	Nu	Afecţiuni limfatice şi ale sângelui	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Daiichi Sankyo, Inc.	internaţional	A Phase 3, Open-Label, Randomized, Multicenter, Controlled Trial To Evaluate The Pharmacokinetics And Pharmacodynamics Of Edoxaban And To Compare The Efficacy And Safety Of Edoxaban With Standard Of Care Anticoagulant Therapy In Pediatric Subjects From Birth To Less Than 18 Years Of Age With Confirmed Venous Thromboembolism (VTE)	III	3						

521	**NC-6004-004A, version 4.1, dated 31.08.2016 VHP2016083**	2016-000084-16	nanoparticle cisplatin (NC-6004) Gemcitabine® (gemcitabine)	Nu	Nu	Afecţiuni oncologice	PPD Romania SRL Ana Maria Tanase E-mail: Ana.Tanase@ppdi.com	NanoCarrier Co, Ltd	internaţional	A Phase 1b/2 Dose Escalation and Expansion Trial of NC-6004 (Nanoparticle Cisplatin) plus Gemcitabine in Patients with Advanced Solid Tumors or Squamous Non-Small Cell Lung, Biliary Tract, and Bladder Cancer	II	45		**28.10.2016**		**06.04.2017**		
522	**H9X-MC-GBGJ, version Initial, dated 19.08.2016**	2016-002494-34	Trulicity® (dulaglutide, LY2189265)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company, SUA	internaţional	A Phase 2, Double-Blind, Placebo-Controlled, 18-Week Trial of Investigational Dulaglutide Doses versus Placebo in Patients with Type 2 Diabetes on Metformin Monotherapy	II	40		**07.02.2017**	**19.01.2017**	**13.02.2017**		
523	**EFC14146, version 1, dated 04.08.2016**	2015-003101-42	dupilumab (SAR231893)	Nu	Da	Afecţiuni ORL	Sanofi Romania SRL Teodora Teodoreanu E-mail: teodora.teodoreanu@sanofi.com Eduard Prisăcariu	Sanofi-Aventis Recherche et Developpement, France	internaţional	A Randomized, 24-Week Treatment, Double-blind, Placebo-controlled Efficacy and Safety Study of Dupilumab Every Other Week, in Patients with Bilateral Nasal Polyposis on a Background Therapy with Intranasal Corticosteroids	III	4		**06.04.2017**	**05.04.2017**	**20.04.2017**		
524	**AL1402ac, version Final 1.0, dated 03.08.2016**	2015-000188-15	house dust mite allergoid (Dermatophagoides pteronyssinus)	Nu	Da	Afecţiuni ale sistemului imunitar	CTG CARDIOMED CRO Simona Piclovnic E-mail: simona.piciovnic@ctgcro.com	Allergopharma GmbH & Co. KG, Germany	internaţional	A multicenter randomized double-blind adaptive placebo-controlled clinical trial for evaluation of efficacy and safety of specific immunotherapy with an aluminium hydroxide-adsorbed allergoid preparation of house dust mite (Dermatophagoides pteronyssinus) in patients with allergic bronchial asthma and with allergic rhinitis or rhinoconjunctivitis	III	165		**27.07.2017**	**26.04.2017**			
525	**M14-533, Amendment 0.01, dated 15.09.2016 VHP2016093**	2016-000674-38	ABT-494	Nu	Nu	Afecţiuni ale sistemului digestiv	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 3 Multicenter, Open-Label Extension (OLE) Study to Evaluate the Long-Term Safety and Efficacy of ABT-494 in Subjects with Ulcerative Colitis (UC)	III	20		**07.04.2017**				
526	**TP-434-021, version 1.1, dated 09.08.2016**	2016-002207-26	eravacycline (TP-434)	Invanz® (ertapenem) Levofloxacin®	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Tetraphase Pharmaceuticals, Inc., USA	internaţional	A Phase 3, Randomized, Double-Blind, Double-Dummy, Multicenter, Prospective Study to Assess the Efficacy and Safety of IV Eravacycline Compared with Ertapenem in Complicated Urinary Tract Infections	III	172		**09.05.2017**	**22.12.2016**	**03.06.2017**		
527	**CA209-714, Revised Protocol 01, Incorporates Amendment 01, dated 19.07.2016**	2016-001645-64	nivolumab (BMS-936558, MDX-1106) ipilimumab (BMS-734016)	Nu	Da	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Double-Blind, Randomized, Two Arm Phase 2 Study of Nivolumab in Combination with Ipilimumab versus Nivolumab in Combination with Ipilimumab Placebo In Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)	II	100		**02.03.2017**	**06.12.2016**	**10.03.2017**		
528	**B9991003, Amendment 3, dated 31 August 2016 VHP2016100**	2015-002429-20	avelumab (MSB0010718C) Inlyta® (axitinib)	Sutent® (sunitinib)	Nu	Afecţiuni oncologice	PPD Romania SRL Manuela Georgiana Botea E-mail: Manuela.Botea@ppdi.com	Pfizer Inc.	internaţional	A Phase 3, 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	III	24		**28.10.2016**		**06.12.2016**		**09.12.2016**
529	**G1T38-02, version 2.0, dated 19.09.2016**	2016-001485-29	G1T38	Nu	Nu	Afecţiuni oncologice	Arensia Exploratory Medicine SRL Alin Marius Stiribu E-mail: alin.stiribu@arensia-em.com	G1 Therapeutics, SUA	internaţional	Phase 1/2 Safety, Pharmacokinetic, and Antitumor Activity Study of G1T38 in Combination with Fulvestrant in Patients with Hormone Receptor-Positive, HER2 Negative Locally Advanced or Metastatic Breast Cancer after Endocrine Failure	II	10						
530	**205832, version 00, dated 19.08.2016**	2016-002843-40	fluticasone furoate (GW685698) umeclidinium bromide (GSK573719)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) SRL Roxana Georgeta Gheorghiu E-mail: roxana.d.gheorghiu@gsk.com	GlaxoSmithKline Research & Development Ltd, UK	internaţional	A Phase IIb, 24 week, randomized, double-blind, 3 arm parallel group study, comparing the efficacy, safety and tolerability of two doses of umeclidinium bromide administered once-daily via a dry powder inhaler, versus placebo, in participants with asthma	II	35		**28.03.2017**		**18.04.2017**		
531	**M14-234, Amendment 0.02, dated 16.09.2016 VHP2016090**	2016-000641-31	ABT-494	Nu	Da	Afecţiuni ale sistemului digestiv	ABBVIE SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of ABT-494 for Induction and Maintenance Therapy in Subjects with Moderately to Severely Active Ulcerative Colitis	III/III	20		**07.04.2017**				
532	**M15-925, Amendment 1, dated 31.08.2016 VHP2016101**	2016-000933-37	ABT-494	Orencia® (abatacept)	Da	Afecţiuni ale sistemului imunitar	ABBVIE SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG	internaţional	A Phase 3, Randomized, Active-Controlled, Double Blind Study Comparing ABT-494 to Abatacept in Subjects with Moderately to Severely Active Rheumatoid Arthritis with Inadequate Response or Intolerance to Biologic DMARDs (bDMARDs) on Stable Conventional Synthetic Disease Modifying Anti-Rheumatic Drugs (csDMARDs)	III	5		**13.02.2017**				
533	**ACE-CL-309, version 0.0, dated 24.03.2016**	2015-004454-17	acalabrutinib (ACP-196)	Zydelig® (idelalisib) MabTherа® (rituximab) bendamustine hydrochloride	Nu	Afecţiuni limfatice şi ale sângelui	Pharmaceutical Research Associates Romania SRL Oana David E-mail: davidoana@prahs.com	Acerta Pharma BV, Olanda	internaţional	A Randomized, Multicenter, Open-Label, Phase 3 Study of Acalabrutinib (ACP-196) Versus Investigator's Choice of Either Idelalisib Plus Rituximab or Bendamustine Plus Rituximab in Subjects with Relapsed or Refractory Chronic Lymphocytic Leukemia	III	8		**18.05.2017**				

534	**GS-US-417-0303, Amendment 1.1, dated 13.09.2016 VHP2016109**	2016-000570-37	filgotinib (GS-6034)	methotrexate	Nu	Afecţiuni ale sistemului musculo-scheletic	Pharmaceutical Research Associates Romania SRL Irina Stratila Email: Stratilairina@prahs.com	Gilead Sciences, Inc.	internaţional	A Randomized, Double-blind, Placebo-and Active-controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 52 Weeks Alone and in Combination with Methotrexate (MTX) to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Are Naïve to MTX Therapy	III	42		**27.10.2016**		**01.03.2017**		
535	**GS-US-417-0301, Amendment 1.1, dated 13.09.2016 VHP2016109**	2016-000568-41	filgotinib (GS-6034)	Humira® (adalimumab)	Nu	Afecţiuni ale sistemului musculo-scheletic	Pharmaceutical Research Associates Romania SRL Victoria Pirzaru E-mail: pirzaruvictoria@prahs.com	Gilead Sciences, Inc.	internaţional	A Randomized, Double-blind, Placebo- and Active-controlled, Multicenter, Phase 3 Study to Assess the Efficacy and Safety of Filgotinib Administered for 52 weeks in Combination with Methotrexate to Subjects with Moderately to Severely Active Rheumatoid Arthritis Who Have an Inadequate Response to Methotrexate	III	27		**27.10.2016**		**06.03.2017**		
536	**GS-US-320-1092, Amendment 1, dated 30.05.2016**	2016-000785-37	tenofovir alafenamide (GS-7340)	Nu	Da	Afecţiuni virale	Pharmaceutical Research Associates Romania SRL Roxana Crisan E-mail: crisanruxandra@prahs.com	Gilead Sciences, Inc., SUA	internaţional	A Randomized, Double-Blind Evaluation of the Pharmacokinetics, Safety, and Antiviral Efficacy of Tenofovir Alafenamide (TAF) in Adolescents with Chronic Hepatitis B Virus Infection	II/III	12			**23.02.2017**			
537	**MR308-3502, version 1.0, dated 26.07.2016**	2016-000593-38	MR308 (tramadol hydrochloride + celecoxib)	Zydol® (tramadol hydrochloride) Celebrex® (celecoxib)	Da	Afecţiuni ale sistemului nervos (analgezice)	INC Research Romania SRL Doina Dobjanschi E-mail: SM_INC_Regulatory_Romania@iNCResearch.com	Mundipharma Research GmbH & Co. KG, Germania	internaţional	A Randomized, Double-Blind, Multicenter, Placebo- and active Comparator-Controled Study to evaluate Efficacy and Safety of MR308 in the Treatment of Acute Pain After Abdominal Hysterectomy Surgery under General Anaesthesia (STARDOM2)	III	150						
538	**200808, version 01, dated 20.09.2016 VHP2016098**	2016-000542-65	daprodustat (GSK1278863)	Aranesp® (darbepoetin alfa)	Nu	Afecţiuni limfatice şi ale sângelui	PPD Romania SRL Ana-Maria Tanase E-mail: Ana.Tanase@ppdi.com	GlaxoSmithKline Research & Development Ltd., UK	internaţional	A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa	III	126		**16.11.2016**		**07.02.2017**		
539	**200807, version 01, dated 20.09.2016 VHP20160999**	2016-000541-31	daprodustat (GSK1278863)	Aranesp® (darbepoetin alfa) Procrit® (epoetin alfa)	Da	Afecţiuni limfatice şi ale sângelui	PPD Romania SRL Ana-Maria Tanase E-mail: Ana.Tanase@ppdi.com	GlaxoSmithKline Research & Development Ltd., UK	internaţional	A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to recombinant human erythropoietin, following a switch from erythropoietin-stimulating agents	III	59		**11.11.2016**		**07.02.2017**		
540	**20110203, dated 31.08.2016**	2016-002299-28	omecamtiv mecarbil (AMG 423)	Nu	Da	Afecţiuni cardiovasculare	Amgen Romania SRL Daniela Stanciu E-mail: daniela.stanciu@amgen.com	Amgen Inc., SUA	internaţional	A Double-blind, Randomized, Placebo-controlled, Multicenter Study to Assess the Efficacy and Safety of Omecamtiv Mecarbil on Mortality and Morbidity in Subjects With Chronic Heart Failure With Reduced Ejection Fraction	III	250		**25.01.2017**	**17.01.2017**			
541	**CAIN457A2322, version 00, dated 24.06.2016**	2015-002423-26	Cosentyx® (secukinumab, AIN457)	Nu	Nu	Afecţiuni ale pielii şi ţesutului conjunctiv	PAREXEL International Romania Manuela Cinca E-mail: europe.cta@novartis.com	Novartis Pharma Services AG, Elveţia	internaţional	A randomized, multicenter Study to evaluate the Effect of secukinumab 300 mg s.c. administered during 52 Weeks to patients suffering from new-onset moderate to severe plaque Psoriasis as early Intervention compared to standard treatment with narrow band UVB (STEPin study)	IV	8			**17.01.2017**			
542	**I6T-MC-AMAG, dated 21.07.2016**	2016-002204-84	LY3074828	Nu	Da	Afecţiuni ale sistemului digestiv	Quintiles Romania SRL Bujor-Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Eli Lilly and Company, SUA	internaţional	A Phase 2, Multicenter, Randomized, Parallel-Arm, Placebo-Controlled Study of LY3074828 in Subjects with Active Crohn's Disease (SERENITY)	II	8			**23.03.2017**			
543	**BPR-PIP-002, version 1.0, dated 09.05.2016**	2013-004615-45	Zevtera® (ceftobiprole medocaril sodium)	ceftriaxone ceftazidime vancomycin	Nu	Afecţiuni ale tractului respirator	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Basilea Pharmaceutica International Ltd., Elveţia	internaţional	A multicentre, randomized, investigator-blind, active-controlled study to evaluate the safety, tolerability, pharmacokinetics and efficacy of ceftobiprole versus intravenous standard-of-care cephalosporin treatment with or without vancomycin in paediatric patients aged from 3 months to less than 18 years with hospital-acquired pneumonia or community-acquired pneumonia requiring hospitalisation	III	39			**23.02.2017**			
544	**CA209-743, version 01, dated 25.05.2016**	2016-001859-43	nivolumab (BMS-936558) ipilimumab (BMS-734016)	Paraplatin® (carboplatin) Cisplatin Neocorp® (cisplatin) Alimta® (pemetrexed disodium)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Phase III, Randomized, Open Label Trial of Nivolumab in combination with Ipilimumab versus Pemetrexed with Cisplatin or Carboplatin as First Line Therapy in unresectable Pleural Mesothelioma	III	40		**15.06.2017**	**22.12.2016**	**04.07.2017**		
545	**2215-CL-0302, version 1.1, dated 05.10.2016**	2016-001643-39	gilteritinib (ASP2215)	Nu	Da	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Mihaela Constantinescu E-mail: Mihaela.ConstantInescu@parexel.com	Astellas Pharma Global Development, Inc. (APGD), SUA	internaţional	A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial of the FLT3 Inhibitor Gilteritinib (ASP2215) Administered as Maintenance Therapy Following Induction/Consolidation Therapy for Subjects with FLT3/ITD AML in First Complete Remission	III	7						
546	**CTHC 007, version 2.1, dated 15.06.2016**	2015-001830-12	Pradaxa® (dabigatran)	Nu	Nu	Afecţiuni cardiovasculare	Medone Research SRL Oana Vittos	University Medical Center of the Johannes Gutenberg University of Mainz, Germania	internaţional	Safety and Efficacy of Low Molecular Weight Heparin for 72 Hours Followed by Dabigatran for the Treatment of Acute Intermediate-Risk Pulmonary Embolism - PEITHO-2	IV	36			**16.02.2017**			

547	**SD-005, version 3, dated 19.09.2016**	2014-002288-14	Zorbilsa® (allantoin, SD-101)	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	HT Research RO Andreea Zaharia E-mail: azaharia@hungarotrial.com	Scioderm, An Amicus Therapeutics Company, SUA	internaţional	A Phase 3, Multi-center, Randomized, Double-Blind, Placebo Controlled Study of the Efficacy and Safety of SD-101 Cream in Patients with Epidermolysis Bullosa	III	25		**30.03.2017**			**10.04.2017**	
548	**WIL-27, version 01, dated 20.09.2016**	2016-003681-34	Wilate® (wilate, human coagulation factor VIII)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	CTG CARDIOMED CRO Simona Piciovnic E-mail: simona.piciovnic@ctgcro.com	Octapharma AG, Elveţia	internaţional	Clinical Study to Investigate the Pharmacokinetics, Efficacy, Safety, and Immunogenicity of Wilate in Previously Treated Patients with Severe Hemophilia A	III	8						
549	**1297.4, version 1.0, dated 30.05.2016**	2016-000612-14	BI 695501	Humira® (adalimumab)	Nu	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Boehringer Ingelheim International GmbH, Germania		BI 695501 versus Humira® in patients with active Crohn's disease: a randomized, double-blind, multicenter, parallel group, non-inferiority trial comparing efficacy, endoscopic improvement, safety, and immunogenicity	III	20			**13.04.2017**			
550	**B9991010, Amendment 1, dated 23.06.2016**	2015-003239-36	avelumab (MSB0010718C)	Nu	Nu	Afecţiuni oncologice	inVentiv Health Clinical Romania SRL Nicoleta Oropeza Soria E-mail: nicoleta.oropezasoria@inventivhealth.com	Pfizer Inc., SUA	internaţional	A Randomized, Open-Label, Multicenter, Phase 3 Study to Evaluate the Efficacy and Safety of Avelumab (MSB0010718C) in Combination with and/or Following Chemotherapy in Patients with Previously Untreated Epithelial Ovarian Cancer (Javelin Ovarian 100)	III	20		**11.05.2017**	**08.12.2016**	**05.07.2017**		
551	**CLCZ696G2301, (version 01, dated 29.06.2016 initial), version 02, dated 25.04.2017**	2016-002154-20	Entresto® (sacubitril + valsartan, LCZ696)	Diovan® (valsartan) Tritace® (ramipril)	Nu	Afecţiuni cardiovasculare	PAREXEL International Romania s.r.l. Manuela Cinca E-mail: Europe.cta@novartis.com	Novartis Pharma Services AG, Elveţia	internaţional	A multi-center, randomized, double-blind, active-controlled, parallel-group Phase 3 study to evaluate the efficacy and safety of LCZ696 compared to ramipril on morbidity and mortality in high risk patients following an acute myocardial infarction	III	250						
552	**B3451002, Amendment 3, dated 01.06.2016 VHP2014136-SW2**	2014-002644-40	PF-06290510	Nu	Da	Infecţii bacteriene şi micoze	inVentiv Health Clinical Romania SRL Monica Angelescu E-mail: monica.angelescu@inventivhealth.com	Pfizer Inc, United States	internaţional	A Phase 2b, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate The Safety and Efficacy of Staphylococcus Aureus 4-Antigen Vaccine (SA4Ag) in Adults Undergoing Elective Open Posterior Spinal Fusion Procedures With Multilevel Instrumentation	II	147		**07.12.2016**	**16.03.2017**			
553	**044-SI, version 1.0, dated 02.09.2016**	2016-002138-63	NETILDEX® ophthalmic gel (netilmicin sulfate+dexamethasone disodium phosphate)	NETILDEX® eye drops solution (netilmicin sulfate+dexamethasone disodium phosphate)	Da	Afecţiuni oculare	MedFocus CRO Octavian Marinescu E-mail: octavian.marinescu@medfocus.ro	S.I.F.I. S.p.A, Italia	internaţional	A prospective, multi-center, controlled, double-blind study to evaluate the efficacy and tolerability of a steroid/antibiotic associated treatment following cataract extraction by means of phaco-emulsification	III	60		**16.03.2017**				
554	**DSE-EDO-01-15-EU, version 1, dated 30.05.2016**	2016-002683-14	Lixiana® (edoxaban, DU-176b)	Sintrom® (acenocumarol) ASS® (acetylsalicylic acid) Clopidogrel® (clopidogrel) Phenoprogamma 3® (phenprocoumon) Efient® (prasugrel) Brilique® (ticagrelor) Previscan® (fluindione) Warfarin® (warfarin sodium)	Nu	Da	Afecţiuni cardiovasculare	Chiltern International Ltd. Emilia Lungu E-mail: emilia.lungu@chiltern.com	Daiichi Sankyo Europe GmbH, Germania	internaţional	Evaluation of the safety and efficacy of an edoxaban-based compared to a vitamin K antagonist-based antithrombotic regimen following successful percutaneous coronary intervention (PCI) with stent placement. (EDOXABAN TREATMENT VERSUS VKA IN PATIENTS WITH AF UNDERGOING PCI - ENTRUST AF-PCI)	III	38		**21.07.2017**				
555	**I1F-MC-RHBY, dated 26.08.2016**	2016-002634-69	Taltz® (ixekizumab, LY2439821)	Nu	Da	Afecţiuni ale sistemului muscub-scheletic	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company, SUA	internaţional	A Multicenter, Long-Term Extension Study of 104 Weeks, Including a Double-Blind, Placebo-Controlled 40-Week Randomized Withdrawal-Retreatment Period, to Evaluate the Maintenance of Treatment Effect of Ixekizumab (LY2439821) in Patients with Axial Spondyloarthritis	III	11		**27.03.2017**				
556	**GS-US-418-3899, version 2.0, dated 27.10.2016 VHP2016126**	2016-002765-58	filgotinib (GS-6034)	Nu	Da	Afecţiuni ale sistemului digestiv	Pharmaceutical Research Associates Romania SRL Oana David E-mail: davidoana@prahs.com	Gilead Sciences, Inc.	internaţional	A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Ulcerative Colitis	III	20		**15.12.2016**	**16.02.2017**			
557	**GS-US-418-3898, version 2.0, dated 27.10.2016 VHP2016125**	2016-001392-78	filgotinib (GS-6034)	Nu	Da	Afecţiuni ale sistemului digestiv	Pharmaceutical Research Associates Romania SRL Oana David E-mail: davidoana@prahs.com	Gilead Sciences, Inc.	internaţional	Combined Phase 2b/3, Double-Blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Ulcerative Colitis	II/III	24		**15.12.2016**	**16.02.2017**	**20.04.2017**		
558	**E2006-G000-303, version 4.0, dated 25.10.2016 VHP2016118**	2015-001463-39	lemborexant (E2006)	Nu	Da	Afecţiuni ale sistemului nervos	PPD Romania SRL Corina Avramescu E-mail: Corina.Avramescu@ppdi.com	Eisai Ltd., UK	internaţional	A Long-Term Multicenter, Randomized, Double-Blind, Controlled, Parallel-Group Study of the Safety and Efficacy of Lemborexant in Subjects With Insomnia Disorder	III	53		**22.12.2016**	**13.03.2017**	**25.04.2017**		
559	**RHB-104-01, version 9.0, dated 03.10.2016**	2015-001179-36	RHB-104 (clarithromycin+rifabutin+clofazimine)	Nu	Da	Afecţiuni ale sistemului digestiv	NEOX s.r.o. Aneta Kocourková E-mail: aneta.kocourkova@neox.cz	RedHill Biopharma Ltd., Israel	internaţional	A Phase III Randomized, Double Blind, Placebo-controlled, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Fixed-dose Combination RHB-104 in Subjects with Moderately to Severely Active Crohn's Disease	III	20						

560	**GS-US-419-3895, Amendment 2, dated 11.11.2016 VHP2016131**	2016-001367-36	filgotinib (GS-6034)	Nu	Da	*Afecţiuni ale sistemului digestiv*	Pharmaceutical Research Associates Romania SRL Ruxandra Popescu E-mail: popescuruxandra@prahs.com	Gilead Sciences, Inc., SUA	internaţional	Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease	III	24		**20.12.2016**	**02.03.2017**	**19.06.2017**		
561	**GS-US-419-3896, Amendment 2, dated 11.11.2016 VHP2016132**	2016-002763-34	filgotinib (GS-6034)	Nu	Da	*Afecţiuni ale sistemului digestiv*	Pharmaceutical Research Associates Romania SRL Ioana Comes E-mail: comesioana@prahs.com	Gilead Sciences, Inc., SUA	internaţional	A Long-Term Extension Study to Evaluate the Safety of Filgotinib in Subjects with Crohn's Disease	III	20		**20.12.2016**	**02.03.2017**			
562	**TransCon hGH CT-301, version 1.0, dated 04.08.2016**	2016-001145-11	TransCon hGH (ACP-011)	Genotropin® (somatropin)	Nu	*Afecţiuni hormonale*	Premier Research Romania SRL Ana Popescu E-mail: ana.popescu@premier-research.com	Ascendis Pharma Endocrinology Division A/S, Danemarca	internaţional	A multicenter, Phase 3, randomized, open-label, active-controlled, parallel-group trial investigating the safety, tolerability, and efficacy of TransCon hGH administered once a week versus standard daily hGH replacement therapy over 52 weeks in prepubertal children with growth hormone deficiency (GHD)	III	20			**09.03.2017**			
563	**AE051-G-13-003, version 2.0, dated 24.03.2016 VHP2016128**	2015-003140-39	JTE-051	Nu	Da	*Afecţiuni ale sistemului imunitar*	PPD Romania S.R.L. Corina Avramescu E-mail: Corina.Avramescu@ppdi.com	Akros Pharma Inc., SUA	internaţional	A Multicenter, Randomized, Double-blind, PlaceboO-controlled, Parallel-group Study to EValuate the Efficacy and Safety of JTE-051 Administered for 12 Weeks to Subjects with Active Rheumatoid Arthritis (MOVE-RA)	II	19		**28.12.2016**		**22.03.2017**		
564	**FER-CARS-06, version 1.1, dated 01.08.2016**	2016-001467-36	Ferinject® (ferric carboxymaltose)	Nu	Da	*Afecţiuni cardiovasculare*	Worldwide Clinical Trials Limited Sarah Bly E-mail: sarah.bly@worldwide.com	Vifor (International) Inc., Elveţia	internaţional	A Randomised, Double-blind Placebo Controlled Trial Comparing the Effect of Intravenous Ferric Carboxymaltose on Hospitalisations and Mortality in Iron Deficient Patients Admitted for Acute Heart Failure (Affirm-AHF)	IV	275						
565	**NN1250-4252, version 2.0, dated 11.11.2016**	2016-002801-20	Toujeo® (insulin glargine) Tresiba® (insulin degludec)	Nu	Nu	*Afecţiuni nutriţionale şi metabolice*	Novo Nordisk Farma SRL Cătălin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S, Danemarca	internaţional	A trial comparing the efficacy and safety of insulin degludec and insulin glargine 300 units/mL in subjects with type 2 diabetes mellitus inadequately treated with basal insulin with or without oral antidiabetic drugs	III	30		**19.07.2017**	**20.03.2017**			
566	**MO29983, version 3, dated 22.11.2016 VHP2016127**	2016-002625-11	atezolizumab (RO5541267, MPDL3280A)	Nu	Nu	*Afecţiuni oncologice*	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffman-La Roche Ltd., Elveţia	internaţional	An open label, single arm, multicenter, safety study of atezolizumab in locally advanced or metastatic urothelial or non-urothelial carcinoma of the urinary tract	III	20		**28.12.2016**				
567	**BAY80-6946/17067, version 4.0, dated 28.07.2016**	2013-003893-29	copanlisib (BAY84-1236)	MabThera® (rituximab)	Da	*Afecţiuni oncologice*	S.C. BAYER S.R.L. Corina Carpa-veche E-mail: ra_romania@bayer.com	Bayer AG (BAG)	internaţional	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	III	22			**10.07.2017**			
568	**CL04041024, Amendment 1, dated 29.09.2016**	2015-005309-35	olokizumab (CDP6038, L04041)	Nu	Nu	*Afecţiuni ale sistemului musculo-scheletic*	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	R-Pharm, Federaţia Rusă	internaţional	A Multicenter, Open-Label, Phase III Study of the Efficacy and Safety of Olokizumab in Subjects with Moderately to Severely Active Rheumatoid Arthritis	III	57						
569	**AL-335-604, version 8.0, dated 13.09.2016**	2016-002845-46	JNJ-64146212-AAA (AL-335) odalasvir (ACH-0143102) Olysio® (simeprevir sodium, JNJ-38733214-AAA)	Nu	Nu	*Afecţiuni virale*	Arensia Exploratory Medicine SRL Alin Stirbu E-mail: alin.stirbu@arensia-em.com	Alios BioPharma, Inc., SUA	internaţional	A Phase 2a, Open-Label Study to Evaluate the Safety, Pharmacokinetics and Efficacy of the Combination of AL-335 and Odalasvir, with or without Simeprevir, in Treatment-Naïve Subjects with Genotype 1, 2 or 3 Chronic Hepatitis C Infection with or without compensated Child Pugh A Cirrhosis	II	19						
570	**M15-889, Amendment 1, dated 11.07.2016**	2016-001097-15	venetoclax (ABT-199)	Nu	Nu	*Afecţiuni oncologice*	Abbvie SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	Open-Label, Single Arm, Phase 3b, Multi-Center Study Evaluating the Impact of Venetoclax on the Quality of Life of Relapsed/Refractory Subjects with Chronic Lymphocytic Leukemia (CLL) Including Those with the 17p Deletion or TP53 Mutation OR Those Who Have Received Prior Treatment with a B-Cell Receptor Inhibitor	III	15						
571	**KCP-330-023, version 1.0, dated 18.11.2016**	2016-003957-14	selinexor (KPT-330) bortezomib dexamethasone	bortezomib dexamethasone	Nu	*Afecţiuni limfatice şi ale sângelui*	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Karyopharm Therapeutics Inc., SUA	internaţional	A Phase 3 Randomized, Controlled, Open-label Study of Selinexor, Bortezomib, and Dexamethasone (SVd) versus Bortezomib and Dexamethasone (Vd) in Patients with Relapsed or Refractory Multiple Myeloma (RRMM)	III	58						
572	**120012A, version 2.0, dated 06.12.2016**	2016-004038-24	MBS2320	Nu	Da	*Afecţiuni ale sistemului musculo-scheletic*	SC Arensia Exploratory Medicine SRL Iuliana Chioveanu E-mail: iuliana.chioveanu@arensia-em.com	MModern Biosciences plc., Marea Britanie	internaţional	A 12-Week, Double-Blind, Placebo-Controlled, Phase 2a Study to Investigate the Safety, Tolerability and Efficacy of MBS2320 in Patients with Active Rheumatoid Arthritis receiving Methotrexate	II	22						

573	**ISK-N102, version 1.0, dated 22.10.2016**	2016-003323-27	NEROFE acetat	Nu	Nu	Afecţiuni limfatice şi ale sângelui	Accelovance Europe Romania SRL Mihaela Phileaga E-mail: mpileaga@accelovance.com	Immune System Key (ISK) Ltd., Israel	naţional	A Phase 2a, Open-Label, Dose-Escalation Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Clinical Effects of Intravenously Administered Nerofe in Subjects with Acute Myelogenous Leukemia or Myelodysplastic Syndrome (AML/MDS)	II	22						
574	**CA209-816, version Initial, dated 30.09.2016**	2016-003536-21	Opdivo® (nivolumab) Yervoy® (ipilimumab)	Vinorelbine® (vinorelbine) Alimta® (pemetrexed) Gemcitabine® (gemcitabine hydrochloride) Docetaxel Hospira® (docetaxel) Cisplatin® (cisplatin) Paraplatin® (carboplatin)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Randomized, Open-Label, Phase 3 Trial of Nivolumab and Ipilimumab versus Platinum-Doublet Chemotherapy in Early Stage NSCLC	III	75			**13.06.2017**			
575	**CA209-907, version 1, dated 10.11.2016**	2016-003731-37	Opdivo® (nivolumab)	Nu	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	An Open-label, single-arm Phase II Safety Study of Nivolumab in Subjects with Advanced or metastatic non-small cell lung cancer who have progressed during or after receiving at least one prior systemic regimen	II	27			**04.05.2017**			
576	**B7921005, Amendment 02, dated 28.11.2016 VHP2016139**	2016-002337-30	PF-06650833	tofacitinib	Da	Afecţiuni ale sistemului musculo-scheletic	PAREXEL International Romania s.r.l. Simona Tudorache E-mail: simona.tudorache@parexel.com	Pfizer Inc., SUA	internaţional	A12 Week Randomized, Double-Blind, Double Dummy, Parallel Group, Active and Placebo-Controlled, Multicenter Study to Assess the Efficacy and Safety Profile of PF-06650833 in Subjects with Active Rheumatoid Arthritis with an Inadequate Response to Methotrexate	II	30		**28.02.2017**		**11.05.2017**		
577	**VIS410-203, version 1.0, dated 21.10.2016**	2016-004009-15	VIS410	Tamiflu® (oseltamivir)	Da	Afecţiuni virale	Pharm-Olam International (UK) Ltd. - Representative Office for Romania Ramona Nicolescu E-mail: ramona.nicolescu@pharm-olam.com	Visterra Inc., SUA	internaţional	Phase 2b, Multicenter, Randomized, Double-blind, Controlled Study to Evaluate the Efficacy and Safety of Intravenous VIS410 in Addition to Oseltamivir (Tamiflu®) Compared With Oseltamivir Alone in Hospitalized Adults With Influenza A Infection Requiring Oxygen Support	II	4						
578	**CQVM149B2303, version 00, dated 19.04.2016**	2016-000472-22	QMF149 (indacaterol acetate+mometasone furoate)	Asmanex Twisthaler® (mometasone furoate)	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Manuela Cinca E-mail: Europe.CTA@Novartis.com	Novartis Pharma Services AG, Elveţia	internaţional	A multi-center, randomized, 12-week treatment, double blind study to assess the efficacy and safety of QMF149 (150/80 microgram) compared with MF Twisthaler® (200 microgram) in adult and adolescent patients with asthma	III	50						
579	**CD101.IV.2.03, Amendment 2, dated 14.09.2016**	2015-005599-51	CD101	Cancidas® (caspofungin) Fluconazole® (fluconazole)	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Cidara Therapeutics Inc., SUA	internaţional	A Phase 2, Multicenter, Randomized, Double-blind Study of the Safety, Tolerability, and Efficacy of Intravenous CD101 vs Intravenous Caspofungin Followed by Oral Fluconazole Step-down in the Treatment of Subjects with Candidemia	II	15			**11.05.2017**			
580	**C38072-AS-30066, dated 09.12.2016**	2016-004661-23	reslizumab (CEP-38072)	Nu	Nu	Afecţiuni ale tractului respirator	PPD Romania SRL Manuela Georgiana Botea E-mail: ManuelaGeorgiana.Botea@ppdi.com	Teva Branded Pharmaceutical Products R&D, Inc., SUA	internaţional	An Open-Label Extension Study of Reslizumab 110-mg Fixed, Subcutaneous Dosing in Patients 12 Years of Age and Older with Severe Eosinophilic Asthma	III	18		**23.06.2017**	**22.05.2017**	**24.07.2017**		
581	**CE01-203, version 3.0, dated 16.12.2016**	2014-004039-37	solithromycin (CEM-101)	ceftriaxone amoxicillin + clavulanic acid amoxicillin azithromycin erythromycin lactobionate erythromycin erythromycin ethylsuccinate	Nu	Infecţii bacteriene şi micoze	Chiltern International Ltd. Emilia Lungu E-mail: emilia.lungu@chiltern.com	Cempra Pharmaceuticals, Inc., SUA	internaţional	A Phase 2/3, Randomized, Open-Label, Multi-center Study to Determine the Safety and Efficacy of Solithromycin in Adolescents (12 to 17 years of age, inclusive) and Children (≥2 months to <12 years of age) with Suspected or Confirmed Community-Acquired Bacterial Pneumonia	II	40						
582	**1245.110, version 1.0, dated 09.11.2016**	2016-002278-11	Jardiance® (empagliflozin)	Nu	Da	Afecţiuni cardiovasculare	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Boehringer Ingelheim International GmbH, Germania	internaţional	A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with preserved Ejection Fraction (HFpEF)	III	262			**26.06.2017**			
583	**3152-301-002, version Final, dated 05.12.2016**	2016-004566-26	cenicriviroc mesylate (TBR-652)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Pharmaceutical Research Associates Romania SRL Ruxandra Popescu E-mail: popescuruxandra@prahs.com	Tobira Therapeutics, a subsidiary of Allergan plc, SUA	internaţional	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Cenicriviroc for the Treatment of Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis	III	32						
584	**205687, version 00, dated 08.12.2016**	2016-004255-70	mepolizumab (SB-240563)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline SRL Roxana Georgeta Gheorghiu E-mail: roxana.d.gheorghiu@gsk.com	GlaxoSmithKline Research & Development Ltd., Marea Britanie	internaţional	A randomised, double-blind, parallel group PhIII study to assess the clinical efficacy and safety of 100 mg SC Mepolizumab as an add on to maintenance treatment in adults with severe bilateral nasal polyps	III	20			**08.06.2017**			
585	**AC-055G202, version 1, dated 07.09.2016 VHP2016147**	2016-003653-15	Opsumit® (macitentan, ACT-064992)	Nu	Da	Afecţiuni cardiovasculare	Covance Clinical &Periapproval Services Limited Andreea Curca E-mail: andreea.curca@covance.com	ACTELION Pharmaceuticals Ltd., Elveţia	internaţional	A multi-center, double-blind, placebo-controlled Phase 2b study to evaluate the efficacy and safety of macitentan in subjects with heart failure with preserved ejection fraction and pulmonary vascular disease	II	10		**28.02.2017**				

586	**LEX-209, version 03, dated 21.10.2016 VHP2016163**	2016-002649-41	Octaplex® (prothrombin complex concentrate)	Beriplex® (prothrombin complex concentrate)	Nu	Afecţiuni limfatice şi ale sângelui	inVentiv Health Clinical Romania S.R.L. Diana Iosep E-mail: diana.iosep@inventivhealth.com	Octapharma Pharmazeutika Produktionsges.m.b.H. Austria	internaţional	A Phase III, randomized, double-blind, multicenter study to assess the efficacy and safety of OCTAPLEX, a four-factor prothrombin complex concentrate (4F-PCC), compared to the 4F-PCC Beriplex® P/N (Kcentra), for the reversal of vitamin K antagonist induced anticoagulation in patients needing urgent surgery with significant bleeding risk	III	70		**15.03.2017**				
587	**EFC14835, (dated 17.01.2017 initial), EFC14835 - Clinical Trial Protocol Version number: 1 (electronic 2.0), dated 04.11.2016, Protocol Amendment 01 Version number: 1 (electronic 1.0), dated 17.01.2017**	2016-002826-35	sotagliflozin (SAR439954, LX4211, LX 4211, LP-802034)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	Sanofi-aventis Recherche & Développement, Franţa	internaţional	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin Added to a Sulfonylurea alone or in combination with Metformin in Patients with Type 2 Diabetes Who Have Inadequate Glycemic Control on a Sulfonylurea Alone or with Metformin	III	23		**31.07.2017**				
588	**D419QC00001, version 1.1, dated 15.12.2016**	2016-001203-23	durvalumab (MEDI4736) tremelimumab (MEDI1123)	Carboplatin® (carboplatin) Cisplatin® (cisplatin) etoposide	Nu	Afecţiuni oncologice	AstraZeneca UK Ltd. Rep Office Romania Francisc Proinov E-mail: francisc.proinov@astrazeneca.com	AstraZeneca AB, Suedia	internaţional	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 Cancer (SCLC)	III	25						
589	**20130286, Amendment 1, dated 30.01.2017**	2015-004735-12	Repatha® (evolocumab, AMG 145) evolocumab (AMG 145)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Amgen Romania SRL Daniela Stanciu E-mail: daniela.stanciu@amgen.com	Amgen Inc., SUA	internaţional	A Double Blind, Randomized, Placebo Controlled, Multicenter Study to Evaluate Safety, Tolerability, and Efficacy on LDL-C of Evolocumab (AMG 145) in Subjects with HIV and with Hyperlipidemia and/or Mixed Dyslipidemia	III	28		**22.06.2017**				
590	**CA209-915, version Original, dated 20.12.2016**	2016-003729-41	Opdivo® (nivolumab, BMS-936558) Yervoy® (ipilimumab, BMS-734016)	Nu	Da	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Phase 3, Randomized Study of Adjuvant Immunotherapy with Nivolumab Combined with Ipilimumab Versus Ipilimumab or Nivolumab Monotherapy after Complete Resection of Stage IIIb/c/d or Stage IV Melanoma	III	34			**18.05.2017**			
591	**CP-4-006, version 1.0, dated 27.11.2016**	2016-003874-42	somatrogon (MOD-4023)	Genotropin® (somatropin)	Nu	Afecţiuni hormonale	SC KCR SA Adriana Rusu E-mail: adriana.rusu@kcrcro.com	OPKO Biologics Ltd., Israel	internaţional	A phase 3, open-label, randomized, multicenter, 12 months, efficacy and safety study of weekly MOD-4023 compared to daily Genotropin® therapy in pre-pubertal children with growth hormone deficiency	III	16						
592	**CSUC-01/16, version 1.1, dated 19.01.2017**	2016-004217-26	cobitolimod (DIMS0150)	Nu	Da	Afecţiuni ale sistemului digestiv	PAREXEL International Romania s.r.l. Simona Tudorache E-mail: simona.tudorache@parexel.com	InDex Pharmaceuticals AB, Suedia	internaţional	A Randomised Dose-Optimisation Study to Evaluate the Efficacy and Safety of Cobitolimod in Moderate to Severe Active Ulcerative Colitis Patients	II	12						
593	**GED-0301-CD-003, dated 25.10.2016**	2015-001924-40	mongersen (GED-0301)	Nu	Da	Afecţiuni ale sistemului digestiv	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Celgene Corporation, SUA	internaţional	A Phase 3, randomized, double-blind, placebo-controlled, multicenter study to investigate the efficacy and safety of mongersen (GED-0301) for the treatment of adult and adolescent subjects with active Crohn's disease	III	16			**06.07.2017**			
594	**CA209-817, Protocol version 02 (incorporates Amendment 04), dated 09.11.2016; protocol amendment 01, 10.08.2016; protocol amendment 05, 4.11.2016; protocol amendment 06, 17.01.2017**	2016-002621-10	Opdivo® (nivolumab, BMS-936558) Yervoy® (ipilimumab, BMS-734016)	Nu	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Phase IIIb/IV Safety Trial of Flat Dose Nivolumab in Combination with Ipilimumab in Participants with Non-Small Cell Lung Cancer	III/IV	50		**31.05.2017**		**14.06.2017**		
595	**1002-043, Amendment 1, dated 08.02.2017 VHP2016152**	2016-003485-11	bempedoic acid (ETC-1002)	Nu	Da	Afecţiuni cardiovasculare	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Esperion Therapeutics Inc., SUA	internaţional	A Randomized, Double-blind, Placebo-controlled Study to Assess the Effects of Bempedoic Acid (ETC-1002) on the Occurrence of Major Cardiovascular Events in Patients with, or at high risk for, Cardiovascular Disease who are Statin Intolerant	III	591		**24.04.2017**				
596	**PR-30-5017-C, version 2.0, dated 22.11.2016**	2015-000952-11	niraparib	Nu	Da	Afecţiuni oncologice	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	TESARO, Inc. SUA	internaţional	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy	III	15			**29.06.2017**			
597	**MS200527-0010, version 2.0, dated 08.02.2017 VHP2016173**	2016-002950-19	M2951	Nu	Da	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Merck KGaA, Germany	internaţional	A Phase II, Randomized, Double-Blind, Placebo-Controlled Dose-Ranging Study To Evaluate the Safety and Efficacy of M2951 in Subjects with Systemic Lupus Erythematosus (SLE)	II	20		**28.03.2017**				
598	**I4V-MC-JAHA, dated 09.02.2017**	2016-004675-52	Olumiant® (baricitinib, LY3009104)	Nu	Da	Afecţiuni ale sistemului imunitar	Eli Lilly Romania Luminiţa Butnaru E-mail: butnaru_luminita@lilly.com	Eli Lilly and Company, SUA	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 24 Week Study Followed by Long-Term Treatment for Evaluation of Efficacy and Safety of Baricitinib in Patients with Active Psoriatic Arthritis	III	18		**06.07.2017**				

599	**205724, version 00, dated 28.11.2016**	2016-003675-21	danirixin (GSK132576H)	Nu	Da	Afecţiuni ale tractului respirator	GlaxoSmithKline (GSK) Romania SRL Mirela Petronela Chiricescu E-mail: mirela.g.chiricescu@gsk.com	GlaxoSmithKline Research & Development Ltd., Marea Britanie	internaţional	Randomised, Double-Blind (Sponsor Open), Placebo-Controlled, Multicentre, Dose Ranging Study to Evaluate the Efficacy and Safety of Danirixin Tablets Administered Twice Daily Compared With Placebo for 24 Weeks in Adult Participants With Chronic Obstructive Pulmonary Disease (COPD)	II	100			**27.06.2017**			
600	**ACE-LY-308, version 00, dated 14.09.2016**	2015-005220-26	acalabrutinib (ACP.-196)	Levact® (bendamustine) MabThera® (rituximab)	Da	Afecţiuni oncologice	INC Research Romania Doina Dobjanschi E-mail: doina.dobjanschi@incresearch.com	Acerta Pharma BV, Olanda	internaţional	A Phase 3, Randomized, Double blind, Placebo controlled, Multicenter Study of Bendamustine and Rituximab (BR) alone Versus in Combination with Acalabrutinib (ACP 196) in Subjects with Previously Untreated Mantle Cell Lymphoma	III	10			**27.07.2017**			
601	**CC-90001-IPF-001, version Initial, dated 08.11.2016**	2016-003473-17	CC-90001	Nu	Da	Afecţiuni ale tractului respirator	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Celgene Corporation, USA	internaţional	A Phase 2, 24-Week Randomized, Double-blind, Placebo-Controlled Multicenter Study, Followed by a 28-Week Treatment Extension, to Evaluate the Efficacy and Safety of CC-90001 in Subjects with Idiopathic Pulmonary Fibrosis	II	9			**26.04.2017**			
602	**AB12008, version 8.0-EU, dated 26.09.2016**	2013-000491-14	masitinib (AB1010)	Nu	Nu	Afecţiuni oncologice	HT Research RO S.R.L. Daniela Marchidanu E-mail: dmarchidanu@hungarotrial.com	AB Science, Franţa	internaţional	A prospective, multicenter, open-label, centrally allocated, active-controlled, phase 2/3 study to evaluate the efficacy and safety of masitinib in combination with gemcitabine versus gemcitabine alone in advanced/metastatic epithelial ovarian cancer patients in second line being refractory to first line platinum treatment or in third line	II/III	26						
603	**IBB-MC-ITRM, version Initial, dated 16.02.2017**	2015-005356-99	insulin lispro ultra rapid formulation (LY900014)	Humalog® (insulin lispro)	Nu	Afecţiuni nutriţionale şi metabolice	Eli Lilly Romania SRL Evelina Gheorghe E-mail: gheorghe_evelina_georgeta@network.lilly.com	Eli Lilly and Company, SUA	internaţional	A Prospective, Randomized, Double-Blind Comparison of LY900014 to Insulin Lispro with an Open-Label Postprandial LY900014 Treatment Group, in Combination with Insulin Glargine or Insulin Degludec, in Adults with Type 1 Diabetes	III	84						
604	**CLEE011A2404, version 01, dated 19.12.2016**	2016-003467-19	ribociclib (LEE011)	Nu	Nu	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Carmen Maria Oltean E-mail: Europe.CTA@novartis.com	Novartis Pharma AG, Elveţia	internaţional	COMPLEEMENT-1: An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of ribociclib (LEE011) in combination with letrozole for the treatment of men and pre/postmenopausal women with hormone receptorpositive (HR+) HER2-negative (HER2-) advanced breast cancer (aBC) with no prior hormonal therapy for advanced disease	III	25						
605	**CPDR001F2301, version 02, dated 27.02.2017**	2016-002794-35	PDR001 Mekinist® (trametinib, TMT212) Tafinlar® (dabrafenib)	Nu	Da	Afecţiuni oncologice	PAREXEL International Romania s.r.l. Diana Campeanu E-mail: Europe.cta@novartis.com	Novartis Pharma AG, Elveţia	internaţional	A randomized, double-blind, placebo-controlled, phase III study comparing the combination of PDR001, dabrafenib and trametinib versus placebo, dabrafenib and trametinib in previously untreated patients with unresectable or metastatic BRAF V600 mutant melanoma	III	12						
606	**BCX7353-202, version 2.0, dated 24.02.2017 VHP 2017606**	2016-001424-55	BCX7353	Nu	Da	Afecţiuni limfatice şi ale sângelui	AMS Advanced Medical Services Ltd Kathryn Hutchinson E-mail: kathryn.hutchinson@ams-europe.com	BioCryst Pharmaceuticals Inc., United States	internaţional	A randomized, double-blind, placebo-controlled, dose-ranging, study to evaluate the efficacy, safety and tolerability of single doses of BCX7353 as an acute attack treatment in subjects with hereditary angioedema	II	10‡			**05.05.2017**			
607	**NGAM-08, version 03, dated 09.03.2017 VHP2017013**	2015-005443-14	Panzyga® (NewGam, immunoglobulin G)	Nu	Da	Afecţiuni ale sistemului imunitar	Premier Research Romania SRL Ana Popescu E-mail: ana.popescu@premier-research.com	Octapharma Pharmazeutika Produktionsges.m.b.H., Austria	internaţional	Prospective, double-blind, randomized, multicenter phase III study evaluating efficacy and safety of three different dosages of NewGam in patients with chronic inflammatory demyelinating poly(radiculo)neuropathy	III	13			**18.04.2017**			
608	**CQAW039A2315, version 00, dated 02.11.2016**	2016-001560-11	fevipiprant (QAW039)	Nu	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Manuela Cinca E-mail: Europe.CTA@Novartis.com	Novartis Pharma AG, Elveţia	internaţional	A 2-treatment period, randomized, placebo-controlled, multicenter parallel-group study to assess the safety of QAW039 when added to existing asthma therapy in GINA steps 3, 4 and 5 patients with uncontrolled asthma	III	73						
609	**CLCZ696D2302, version 01, dated 24.01.2017**	2016-003410-28	Entresto® (sacubitril + valsartan, LCZ696)	Diovan® (valsartan) Enalapril®, EnaHEXAL® (enalapril)	Da	Afecţiuni cardiovasculare	PAREXEL International Romania s.r.l. Andrada Ciorobîtca E-mail: Europe.CTA@Novartis.com	Novartis Pharma AG, Elveţia	internaţional	A 24-week, randomized, double-blind, multi-center, parallel group, active controlled study to evaluate the effect of LCZ696 on NT-proBNP, symptoms, exercise function and safety compared to individualized medical management of comorbidities in patients with heart failure and preserved ejection fraction	III	112						
610	**R2810-ONC-1624, version 3.0, dated 15.03.2017**	2016-004407-31	REGN2810	Carboplatin® (carboplatin) Cisplatin® (cisplatin) Gemcitabine® (gemcitabine) Paclitaxel® (paclitaxel) Armisarte® (pemetrexed)	Nu	Afecţiuni oncologice	ICON Clinical Research SRL Alin Balaiau E-mail: ICONRomania@iconplc.com	Regeneron Pharmaceuticals, Inc., USA	internaţional	A Global, Randomized, Phase 3, Open-Label Study of REGN2810 (Anti PD 1 Antibody) versus Platinum Based Chemotherapy in First Line Treatment of Patients with Advanced or Metastatic PD L1 + Non-Small Cell Lung Cancer	III	4						
611	**GS-US-417-0304, Amendment 1.1, dated 06.03.2017 VHP2017012**	2016-003630-25	filgotinib (GS-6034)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Pharmaceutical Research Associates Romania SRL Irina Strătilă E-mail: straitairina@prahs.com	Gilead Sciences, Inc., USA	internaţional	A Multicenter, Double-blind, Long Term Extension Study to Assess the Safety and Efficacy of Filgotinib in Subjects with Rheumatoid Arthritis	III	69			**25.04.2017**			

612	**K-877-302, version 2, dated 27.03.2017 VHP2016177**	2016-003818-26	pemafibrate (K-877)	Nu	Da	Afecţiuni cardiovasculare	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Kowa Research Institute, Inc., USA	internaţional	Pemafibrate to Reduce cardiovascular OutcoMes by reducing triglycerides IN patiENts with diabeTes (PROMINENT)	III	343		**25.04.2017**				
613	**CQVM149B2208, version 00, dated 20.03.2017**	2016-005164-34	QVM149 (indacaterol acetate + glycopyrronium bromide + mometasone furoate)	Seretide® (fluticasone + salmeterol)	Da	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Dominica Tone E-mail: europe.cta@novartis.com	Novartis Pharma AG, Elveţia	internaţional	A randomized, double-blind, double dummy, active-controlled, 3-period complete cross-over study to assess the bronchodilator effect and safety of two doses of QVM149 compared to a fixed dose combination of salmeterol/fluticasone in patients with asthma	II	30						
614	**CA212-016, Revised Protocol no. 05 Incorporates amendment(s) 06, dated 29.03.2017**	2016-004275-40	ulocuplumab (BMS-936564) ARA-cell® (cytarabine)	Nu	Nu	Afecţiuni oncologice	Bristol Myers Squibb Maketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Phase 1/2, Open-label Randomized Study of Ulocuplumab (BMS-936564) In Combination with Low Dose Cytarabine in Subjects with Newly Diagnosed Acute Myeloid Leukemia	II	30			**19.07.2017**			
615	**LSK-AM301, version 3.0, dated 03.02.2017**	2016-003984-20	apatinib	Nu	Da	Afecţiuni oncologice	Chiltern International Limited Emilia Lungu E-mail: emilia.lungu@chiltern.com	LSK BioPartners, Inc., USA	internaţional	A Prospective, Randomized, Double-Blinded, Placebo-Controlled, Multinational, Multicenter, Parallel-group, Phase III Study to Evaluate the Efficacy and Safety of Apatinib plus Best Supportive Care (BSC) compared to Placebo plus BSC in Patients with Advanced or Metastatic Gastric Cancer (GC)	III	10			**31.07.2017**			
616	**CVAY736A2201, version 01, dated 12.01.2017**	2016-003292-22	VAY736	Nu	Da	Afecţiuni ale sistemului imunitar	PAREXEL International Romania s.r.l. Manuela Cinca E-mail: Europe.cta@novartis.com	Novartis Pharma AG, Elveţia	internaţional	A randomized, double-blind, placebo-controlled multicenter phase 2 dose-ranging study to assess the safety and efficacy of multiple VAY736 doses administered subcutaneously in patients with moderate to severe primary Sjogren's Syndrome	II	8						
617	**PRAN-16-52, version 2.0, dated 15.03.2017**	2016-004724-34	pracinostat (SB939)	Nu	Da	Afecţiuni oncologice	Clinipace Worldwide - Accovion SRL Carmen Vizman E-mail: cvizman@clinipace.com	Helsinn Healthcare SA, Suedia	internaţional	A Phase III, Double-Blind, Placebo-Controlled, Multicenter, Randomized Study Of Pracinostat In Combination With Azacitidine In Patients ≥18 Years With Newly Diagnosed Acute Myeloid Leukemia Unfit For Standard Induction Chemotherapy	III	24						
618	**CNTO1959PSA3002, version A0, dated 16.03.2017**	2016-001224-63	guselkumab (CNTO1959)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	Johnson&Johnson Romania SRL Irina Toma E-mail: itoma@its.jnj.com	Janssen-Cilag International N.V., Belgia	internaţional	A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study Evaluating the Efficacy and Safety of Guselkumab Administered Subcutaneously in Subjects with Active Psoriatic Arthritis	III	22						
619	**BIA-2093-211, version Final 2.0, dated 21.12.2016**	2012-001091-11	eslicarbazepine acetate (BIA 2-093)	Nu	Nu	Afecţiuni ale sistemului nervos	SC Scope International SRL Tudor Mitu E-mail: tmitu@scope-international.com	BIAL - Portela & Ca, S.A., Portugalia	internaţional	Open-label, 2-dose level trial to evaluate pharmacokinetics, safety, and tolerability of eslicarbazepine acetate (ESL) as adjunctive therapy in infants with refractory epilepsy with partial-onset seizures aged from 1 month to <2 years	II	10			**04.07.2017**			
620	**BIA-2093-211EXT, version Final 1.0, dated 21.12.2016**	2016-001072-29	eslicarbazepine acetate (BIA 2-093)	Nu	Nu	Afecţiuni ale sistemului nervos	SC Scope International SRL Tudor Mitu E-mail: tmitu@scope-international.com	BIAL - Portela & Ca, S.A., Portugalia	internaţional	Open-label, 2-dose level trial to evaluate pharmacokinetics, safety, and tolerability of eslicarbazepine acetate (ESL) as adjunctive therapy in infants with refractory epilepsy with partial-onset seizures aged from 1 month to <2 years – 1-year extension	II	10			**04.07.2017**			
621	**CA209-648, Revised Protocol no. 01, Incorporates amendment(s) 02, dated 21.12.2016**	2016-001514-20	Opdivo® (nivolumab, BMS-936558) Yervoy® (ipilimumab, BMS-734016)	Cisplatin Neocorp® (cisplatin) Cisplatin Ebewe® (cisplatin) Cisplatin Teva® (cisplatin) 5-Fluorouracil-Ebewe® (5-fluorouracil) 5-FU MEDAC® (5-fluorouracil)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Randomized Phase 3 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	III	20			**27.07.2017**			
622	**M16-127, Amendment 1, dated 20.01.2017**	2016-004182-60	glecaprevir + pibrentasvir (ABT-493 + ABT-530)	Nu	Nu	Afecţiuni virale	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Multicenter, Open-Label Study to Evaluate the Efficacy and Safety of Glecaprevir/Pibrentasvir in Renally-Impaired Adults with Chronic Hepatitis C Virus Genotype 1 – 6 Infection (EXPEDITION-5)	III	18						
623	**LRD.2016.STREAM2, version 3, dated 10.01.2017**	2016-001642-26	Metalyse® (tenecteplase) Clopidogrel® (clopidogrel)	Nu	Nu	Afecţiuni cardiovasculare	CONFIDENCE Pharmaceutical Research, LLC Daniela Pirvu	Leuven Research & Development (LRD) at University of Leuven, Belgium	internaţional	STREAM-2 (STrategic Reperfusion in elderly patients Early After Myocardial Infarction)	IV	200						
624	**E2609-G000-301, version 03, dated 06.02.2017**	2016-003928-23	elenbecestat (E2609)	Nu	Da	Afecţiuni ale sistemului nervos	inVentiv Health Clinical Romania SRL Kubanda Bianka E-mail: bianka.kubanda@inventivhealth.com	Eisai Ltd., UK	internaţional	A Placebo-Controlled, Double-Blind, Parallel-Group, 24-Month Study to Evaluate the Efficacy and Safety of E2609 in Subjects with Early Alzheimer's Disease	III	30						

625	**E7080-G000-218, Amendment 1, dated 24.04.2017 VHP2017014**	2016-002778-11	Kisplyx® (lenvatinib, E7080) Afinitor® (everolimus)	Nu	Da	Afecţiuni oncologice	PPD Romania S.R.L. Corina Avramescu E-mail: Corina.Avramescu@ppdi.com	Eisai Limited	internaţional	A Randomized, Double-blind, Phase 2 Trial to Assess Safety and Efficacy of Lenvatinib at Two Different Starting Doses (18 mg vs. 14 mg QD) in Combination with Everolimus (5 mg QD) in Renal Cell Carcinoma Following One Prior VEGF-Targeted Treatment	II	26		**25.05.2017**	**26.06.2017**			
626	**205203, version 01, dated 13.01.2017**	2017-000184-32	Nucala® (mepolizumab, SB240563)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	GlaxoSmithKline Romania SRL Mirela Petronela Chiricescu E-mail: mirela.g.chiricescu@gsk.com	GlaxoSmithKline Research & Development Ltd., Marea Britanie	internaţional	A multi-centre, open-label extension, safety study to describe the longterm clinical experience of mepolizumab in participants with hypereosinophilic syndrome (HES) from Study 200622	III	5						
627	**RPL554-CO-203, version 02, dated 18.04.2017 VHP2017036**	2016-005205-40	RPL554	Nu	Da	Afecţiuni ale tractului respirator	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Verona Pharma plc, UK	internaţional	A Phase IIb, randomized, double blind, placebo controlled, dose ranging study to assess the effect of RPL554 in patients with moderate to severe COPD	II	40		**25.05.2017**	**19.06.2017**	**07.07.2017**		
628	**TOZ-CL06, version 2.0, dated 03.02.2017**	2016-003961-25	tozadenant (TOZ)	Nu	Nu	Afecţiuni ale sistemului nervos	AMS Advanced Medical Services Ltd Kathryn Hutchinson E-mail: kathryn.hutchinson@ams-europe.com	Biotie Therapies, USA	internaţional	A Multicenter, Open-Label Study to Evaluate the Safety and Tolerability of Tozadenant as Adjunctive Therapy in Levodopa-Treated Patients with Parkinson's Disease Experiencing End of Dose "Wearing-Off"	III	33						
629	**16-OBE2109-009, version 1.0, dated 08.02.2017**	2016-004059-53	OBE2109 Klovance® (estradiol hemihydrate + norethisterone acetate) Evianа® (estradiol hemihydrate + norethisterone acetate)	Nu	Da	Afecţiuni ale sistemului urinar şi reproducător feminin	Chiltern International Limited Emilia Lungu E-mail: emilia.lungu@chiltern.com	ObsEva SA, Elveţia	internaţional	A Phase 3, multicentre, randomized, double-blind, placebo controlled study investigating the efficacy and safety of daily oral administration of OBE2109 alone and in combination with add-back therapy for the management of heavy menstrual bleeding associated with uterine fibroids in premenopausal women	III	54						
630	**MK-7625A-035, version 00, dated 21.03.2017**	2016-004820-41	Zerbaxa® (ceftolozane + tazobactam, MK-7625A) Metronidazole® (metronidazole)	Merrem® (meropenem)	Da	Infecţii bacteriene şi micoze	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., USA	internaţional	A Phase 2, Randomized, Active Comparator-Controlled, Multicenter, Double-Blind Clinical Trial to Study the Safety and Efficacy of Ceftolozane/Tazobactam (MK-7625A) Plus Metronidazole Versus Meropenem in Pediatric Subjects with Complicated Intra- Abdominal Infection	II	7						
631	**MK-7625A-034, version 00, dated 21.03.2017**	2016-004153-32	Zerbaxa® (ceftolozane + tazobactam, MK-7625A)	Merrem® (meropenem)	Nu	Infecţii bacteriene şi micoze	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., USA	internaţional	A Phase 2, Randomized, Active Comparator-Controlled, Multicenter, Double-Blind Clinical Trial to Study the Safety and Efficacy of Ceftolozane/Tazobactam (MK-7625A) Versus Meropenem in Pediatric Subjects with Complicated Urinary Tract Infection, Including Pyelonephritis	II	12						
632	**1602T0832, Version 4.2 (Amendment 3.2 – EU only), dated 03.05.2017 VHP2017026**	2016-002688-32	S-033188	Tamiflu® (oseltamivir)	Da	Afecţiuni virale	Pharmaceutical Research Associates Romania SRL Ruxandra Popescu E-mail: popescuruxandra@prahs.com	Shionogi Ltd., Marea Britanie	internaţional	A Phase 3, Multicenter, Randomized, Double-blind Study of a Single Dose of S-033188 Compared with Placebo or Oseltamivir 75 mg Twice Daily for 5 Days in Patients with Influenza at High Risk of Influenza Complications	III	41		**09.06.2017**				
633	**MA30143, version 3, dated 28.03.2017**	2016-002937-31	ocrelizumab (RO4964913/F07-01)	Nu	Nu	Afecţiuni ale sistemului nervos	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Elveţia	internaţional	An Open-Label, single-arm study to evaluate the effectiveness and safety of Ocrelizumab in patients with early stage relapsing remitting multiple sclerosis	III	20						
634	**181601, dated 31.01.2017**	2016-003671-22	SM101	Nu	Da	Afecţiuni ale sistemului imunitar	Quintiles Romania SRL Bujor Eugen Almasan E-mail: bujor-eugen.almasan@quintiles.com	Baxalta Innovations GmbH, Austria	internaţional	A Phase 2b, Multidose, Multicenter, Double-blind, Placebo-controlled, 24 Week Study to Evaluate the Efficacy and Safety of Intravenous Infusion with Recombinant Human Soluble Fc-gamma IIB Receptor SM101 in Subjects with Systemic Lupus Erythematosus (SLE)	II	10						
635	**FFIS/2016/02/ST, version 1.0, dated 03.01.2017**	2016-005206-19	pravastatin	Nu	Da	Afecţiuni cardiovasculare	The Fetal Medicine Foundation Kypros Nicolaides E-mail: thanos@fetalmedicine.com	Fundación para la Formación e Investigación Sanitaria (FFIS), Spania	internaţional	Randomised Controlled Trial with Pravastatin versus Placebo for Prevention of Preeclampsia	III	46						
636	**EFC14153, version 1, dated 04.08.2016**	2016-001607-23	dupilumab (SAR231893)	Nu	Da	Afecţiuni ale tractului respirator	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	Sanofi-Aventis Recherche & Développement	internaţional	A Randomized, Double-blind, Placebo-controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Dupilumab in Children 6 to <12 Years of Age with Uncontrolled Persistent Asthma	III	9						
637	**MO39196, version 2, dated 17.05.2017 VHP2017029**	2016-004024-29	atezolizumab (RO5541267, MPDL3280A)	Paclitaxel® /Sindaxel® (paclitaxel)	Da	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Elveţia	internaţional	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	III	10		**22.06.2017**				

638	**15-102-14, Amendment 3.0, dated 27.03.2017**	2016-002453-38	NKTR-102 (etirinotecan pegol)	Halaven® (eribulin) Vinorelbine® (vinorelbine) Gemcitabine® (gemcitabine) Paclitaxel® (paclitaxel) Docetaxel® (docetaxel) Abraxane® (Nab-paclitaxel)	Nu	Afecţiuni oncologice	Covance Clinical and Periapproval Services Limited Ilinca Nicolescu E-mail: Ilinca.Nicolescu@covance.com	Nektar Therapeutics, USA	internaţional	A Phase 3 Open-Label, Randomized, Multicenter Study of NKTR-102 versus Treatment of Physician's Choice (TPC) in Patients with Metastatic Breast Cancer Who Have Stable Brain Metastases and Have Been Previously Treated with an Anthracycline, a Taxane, and Capecitabine	III	22						
639	**CA209-9ER, version Initial, dated 08.03.2017**	2017-000759-20	Opdivo® (nivolumab, BMS-936558) Yervoy® (ipilimumab, BMS-734016) Carbometyx® (cabozantinib, XL184)	Sutent® (sunitinib)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Phase 3, Randomized, Open-Label Study of Nivolumab Combined with Cabozantinib or Nivolumab and Ipilimumab Combined with Cabozantinib versus Sunitinib in Participants with Previously Untreated, Advanced or Metastatic Renal Cell Carcinoma	III	25						
640	**CAIN457H3301, version 00, dated 07.02.2017**	2017-000401-21	Cosentyx® (secukinumab, AIN457)	Nu	Da	Afecţiuni ale sistemului musculo-scheletic	PAREXEL International Romania s.r.l. Manuela Cinca E-mail: Europe.CTA@Novartis.com	Novartis Pharma AG, Elveţia	internaţional	SKIPPAIN (Speed of onset of SecuKinumab-Induced relief from Pain in Patients with Axial SpoNdyloarthritis) A 24-week, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of secukinumab in controlling spinal pain in patients with axial spondyloarthritis	III	16						
641	**M16-289, PA 2, dated 19.05.2017 VHP2017025**	2016-003726-17	rovalpituzumab tesirine (SC16LD6.5) topotecan	Nu	Nu	Afecţiuni oncologice	Abbvie SRL Corina Ana Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Randomized, Open-Label, Multicenter, Phase 3 Study of Rovalpituzumab Tesirine Compared with Topotecan for Subjects with Advanced or Metastatic DLL3high Small Cell Lung Cancer (SCLC) who have First Disease Progression During or Following Front-Line Platinum-Based Chemotherapy (TAHOE)	III	36	**27.07.2017**					
642	**M16-135, Amendment 1, dated 25.04.2017 VHP2017044**	2016-004967-38	glecaprevir + pibrentasvir (ABT-493 + ABT-530)	Nu	Nu	Afecţiuni virale	Abbvie SRL Corina Ana Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Single Arm, Open-label Study to Evaluate the Efficacy and Safety of Glecaprevir (GLE)/Pibrentasvir (PIB) in Treatment Naïve Adults with Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 4, 5 or 6 Infection and Compensated Cirrhosis	III	40	**27.07.2017**					
643	**MK-8259-038, version 01, dated 21.03.2017**	2015-004020-65	Simponi® (golimumab)	Nu	Da	Afecţiuni ale sistemului imunitar	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., USA	internaţional	A Phase-IV, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial to Evaluate the Efficacy and Safety of Golimumab (MK-8259 [SCH 900259]) After Treatment Withdrawal, Compared With Continued Treatment (Either Full or Reduced-Treatment Regimen), In Subjects With Non-Radiographic Axial Spondyloarthritis	IV	28						
644	**MK-6072-001, version 00, dated 25.04.2017**	2017-000070-11	Zinplava® (bezlotoxumab, MK-6072)	Nu	Da	Infecţii bacteriene şi micoze	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., USA	internaţional	A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of a Single Infusion of Bezlotoxumab (MK 6072, Human Monoclonal Antibody to C. difficile Toxin B) in Children Aged 1 to <18 Years Receiving Antibacterial Drug Treatment for C. difficile Infection (MODIFY III)	III	12						
645	**AB15003, version 1.0/EU, dated 08.09.2016**	2016-001447-39	masitinib mesylate (AB1010)	Nu	Da	Afecţiuni limfatice şi ale sângelui	EastHORN Clinical Services in CEE S.R.L. Anca Brasoveanu E-mail: anca.brasoveanu@easthorn.eu	AB Science, Franţa	internaţional	A 24-week with possible extension, prospective, multicenter, randomized, double blind, placebo-controlled, 2-parallel group with a randomization 1:1, phase 3 study to compare efficacy and safety of masitinib to placebo in treatment of patients with Smouldering or Indolent Severe Systemic mastocytosis with handicap, unresponsive to optimal symptomatic treatment	III	25i						
646	**MO39129, version 2.0, dated 02.06.2017 VHP2017042**	2016-004366-25	emicizumab (ACE910, RO5534262)	Nu	Nu	Afecţiuni şi anomalii congenitale, ereditare şi neonatale	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Elveţia	internaţional	A single-arm, multicenter phase IIIb clinical trial to evaluate the safety and tolerability of prophylactic emicizumab in hemophilia A patients with inhibitors	III	10						
647	**KBP042/CD/003, version 1.0, dated 06.04.2017**	2017-001061-24	KBP-042	Nu	Da	Afecţiuni nutriţionale şi metabolice	Nordic Bioscience Clinical Development A/S Eugen Ştefănuţ E-mail: est@nordicbio.com	KeyBioscience AG, Elveţia	internaţional	A Double-blind, Placebo-controlled, Randomized Study to Evaluate the Efficacy and Safety of KBP-042 in Patients with Type 2 Diabetes	II	60						
648	**CR6086-2-02, version 01, dated 28.03.2017**	2016-004834-11	CR6086	Methotrexate® (methotrexate)	Nu	Afecţiuni ale sistemului musculo-scheletic	Nordic Bioscience Clinical Development A/S Eugen Ştefănuţ E-mail: est@nordicbio.com	Rottapharm Biotech S.r.l., Italia	internaţional	A randomized, double blind, placebo-controlled, dose response, phase II, multicentre trial to evaluate the efficacy, safety and pharmacokinetics of oral CR6086 administered at the doses of 30, 90 or 180 mg bid for 12 weeks in combination with methotrexate, in DMARD-naive patients with early rheumatoid arthritis	II	45						
649	**ALN-CC5-004, version 01, dated 25.04.2017**	2017-001082-24	cemdisiran (ALN-CC5, ALN-62643)	Nu	Nu	Afecţiuni limfatice şi ale sângelui	PPD Romania SRL Manuela Georgiana Botea E-mail: ManuelaGeorgiana.Botea@ppdi.com	Alnylam Pharmaceuticals, Inc., USA	internaţional	A Phase 2, Open Label, Multicenter Study of ALN-CC5 Administered Subcutaneously in Adult Patients with Atypical Hemolytic Uremic Syndrome	II	4						
650	**I3Y-MC-JPCF, version Initial, dated 10.03.2017 VHP2017057**	2016-004362-26	abemaciclib (LY2835219)	Nu	Nu	Afecţiuni oncologice	Eli Lilly Romania SRL Luminita Butnaru E-mail: butnaru_luminita@lilly.com	Eli Lilly and Company, USA	internaţional	A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer	III	45	**10.07.2017**					

651	**MK-5592-069, version 04, dated 01.08.2016**	2011-003938-14	posaconazole (SCH56592, MK-5592)	Vfend® (voriconazole)	Da	Infecţii bacteriene şi micoze	Merck Sharp & Dohme Romania SRL Florina Prundaru E-mail: florina.prundaru@merck.com	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., USA	internaţional	A Phase 3 Randomized Study of the Efficacy and Safety of Posaconazole versus Voriconazole for the Treatment of Invasive *Aspergillosis* in Adults and Adolescents (Phase 3; Protocol No. MK-5592-069)	III	6						
652	**OOC-ACM-303, version 4.0, dated 24.04.2017**	2017-000737-31	Mycapssa® (octreotide acetate)	Nu	Da	Afecţiuni hormonale	Pharm-Olam International (UK) Ltd. Ramona Nicolescu E-mail: ramona.nicolescu@pharm-olam.com	Chiasma, Inc., USA	internaţional	A phase 3, randomized, double-blind, placebo-controlled, multicenter study to evaluate efficacy and safety of octreotide capsules in patients who previously tolerated and demonstrated biochemical control on injectable somatostatin receptor ligands (SRL) treatment	III	5						
653	**BO39633, version 2, dated 14.06.2017 VHP2017047**	2016-005189-75	atezolizumab (MPDL3280A, RO5541267) Avastin® (bevacizumab)	Sutent® (sunitinib)	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd., Elveţia	internaţional	An Open-Label, Multicenter Extension Study In Patients Previously Enrolled In A Genentech- And/Or F. Hoffmann La Roche Ltd-Sponsored Atezolizumab Study	III	3		**14.07.2017**				
654	**CV181375/D1680C00019, version 02, dated 04.04.2017**	2015-005042-66	Forxiga® (dapagliflozin) Onglyza® (saxagliptin)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Pharmaceutical Research Associates Romania SRL Ruxandra Crisan Email: crisanruxandra@prahs.com	AstraZeneca AB, Suedia	internaţional	A 26 Week, Multicenter, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Phase 3 Trial with a 26 Week Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 5 and 10 mg, and Saxagliptin 2.5 and 5 mg in Pediatric Patients with Type 2 Diabetes Mellitus who are between 10 and below 18 years of age	III	15						
655	**NN1218-4113, (version 2.0, dated 28.03.2017 initial), version 3.0, dated 09.06.2017 VHP2017061**	2016-000878-38	Fiasp® (insulin aspart) Tresiba® (insulin degludec)	Novorapid® (insulin aspart)	Nu	Afecţiuni nutriţionale şi metabolice	Novo Nordisk Farma SRL Catalin Bucerzan E-mail: catb@novonordisk.com	Novo Nordisk A/S, Danemarca	internaţional	Efficacy and Safety of Fast-acting Insulin Aspart Compared to NovoRapid® both in Combination with Insulin Degludec with or without Metformin in Adults with Type 2 Diabetes	III	60		**21.07.2017**				
656	**M15-572, Incorporating Amendment 1 and Amendment 1.01, dated 20.06.2017 VHP2017054**	2016-004130-24	upadacitinib (ABT-494)	Humira® (adalimumab)	Da	Afecţiuni ale sistemului imunitar	ABBVIE SRL Ana Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Phase 3, Randomized, Double-Blind, Study Comparing ABT-494 to Placebo and to Adalimumab in Subjects with Active Psoriatic Arthritis Who Have a History of Inadequate Response to at Least One Non-Biologic Disease Modifying Anti-Rheumatic Drug (DMARD) – SELECT – PsA 1	III	25						
657	**CA209-9LA, version Initial, dated 10.05.2017**	2017-001195-35	Opdivo® (nivolumab, BMS-936558) Yervoy® (ipilimumab, BMS-734016)	Paraplatin® (carboplatin) Taxol® (paclitaxel) Alimta® (pemetrexed disodium) Cisplatin NeoCorp® (cisplatin) Cisplatin Ebewe® (cisplatin) Cisplatin Teva® (cisplatin)	Nu	Afecţiuni oncologice	Bristol-Myers Squibb Marketing Services SRL Ema Vasilescu Mincu E-mail: ema.mincu@bms.com	Bristol-Myers Squibb International Corporation, Belgia	internaţional	A Study of Nivolumab plus Ipilimumab in Combination with Chemotherapy vs Chemotherapy alone as First Line Therapy in Stage IV Non-Small Cell Lung Cancer (NSCLC)	III	40						
658	**XL184-401, Amendment 3, dated 01.09.2015**	2013-003402-40	cabozantinib (XL184)	Cometriq® (cabozantinib)	Da	Afecţiuni oncologice	PPD Romania SRL Brindusa Ilse Stoica E-mail: brindusa.stoica@ppdi.com	Exelixis, Inc., USA	internaţional	A 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	IV	12						
659	**MO29872, version 2, dated 29.06.2017 VHP2017029**	2015-004105-16	atezolizumab (RO5541267, MPDL3280A) Gemcitabin® (gemcitabine)	Navelbine® (vinorelbine tartrate, PM0259) Vinorelbine Sandoz® (vinorelbine tartrate) Vinorelbine NCB (vinorelbine tartrate) Navelbine® (vinorelbine tartrate)	Nu	Afecţiuni oncologice	Roche Romania SRL Laura Cojocaru-Taran E-mail: laura.taran@roche.com	F. Hoffmann-La Roche Ltd, Elveţia	internaţional	A Phase III, Open-label, multicenter, randomized study to investigate the efficacy and safety of atezolizumab compared with chemotherapy in patients with treatment-naïve advanced or recurrent (Stage IIIB not amenable for multimodality treatment) or metastatic (Stage IV) non-small cell lung cancer who are deemed unsuitable for platinum-containing therapy	III	12		**27.07.2017**				
660	**BAY80-6946/17833, version 4.0, dated 30.03.2017**	2015-001088-38	copanlisib (BAY84-1236)	Nu	Da	Afecţiuni oncologice	SC Bayer SRL Corina Carpa-veche E-mail: ra_romania@bayer.com	Bayer AG (BAG)	internaţional	A Phase III, randomized, double-blind, controlled, multicenter study of intravenous PI3K inhibitor copanlisib in combination with standard immunochemotherapy versus standard immunochemotherapy in patients with relapsed indolent non-Hodgkin's lymphoma (iNHL) - CHRONOS-4	III	30						
661	**M16-006, Amendment 1, dated 05.07.2017 VHP2017069**	2016-003123-32	risankizumab (ABBV-066)	Nu	Da	Afecţiuni ale sistemului digestiv	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Crohn's Disease	III	15						
662	**M15-991, Amendment 2, dated 05.07.2017 VHP2017068**	2016-003190-17	risankizumab (ABBV-066)	Nu	Da	Afecţiuni ale sistemului digestiv	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study to Assess the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Crohn's Disease Who Failed Prior Biologic Treatment	III	15						
663	**M16-000, Amendment 2, dated 05.07.2017 VHP2017070**	2016-003191-50	risankizumab (ABBV-066)	Nu	Da	Afecţiuni ale sistemului digestiv	Abbvie SRL Corina Ionescu E-mail: corina.ionescu@abbvie.com	AbbVie Deutschland GmbH & Co. KG, Germania	internaţional	A Multicenter, Randomized, Double-Blind, Placebo Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Crohn's Disease Who Responded to Induction Treatment in M16-006 or M15-991	III	30						

664	**EFC15166, dated 10.05.2017**	2016-004906-32	sotagliflozin (SAR439954)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	Sanofi-aventis Recherche & Développement, Franţa	internaţional	A Randomized, Double-blind, Placebo-controlled, 3-arm, Parallel group 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Severe Renal Impairment who have Inadequate Glycemic Control	III	16						
665	**EFC14837, dated 11.05.2017**	2016-004889-26	sotagliflozin (SAR439954)	Nu	Da	Afecţiuni nutriţionale şi metabolice	Sanofi Romania SRL Alexandra Voicu E-mail: alexandra.voicu@sanofi.com	Sanofi-aventis Recherche & Développement, Franţa	internaţional	A Randomized, Double-blind, Placebo-controlled, 3-arm, Parallel-group 52-week Multicenter Study to Evaluate the Efficacy and Safety of Sotagliflozin in Patients with Type 2 Diabetes Mellitus and Moderate Renal Impairment who have Inadequate Glycemic Control	III	46						
666	**CF101-301RA, version 2.0, dated 12.04.2017**	2016-003682-26	CF101	methotrexate	Da	Afecţiuni ale sistemului musculo-scheletic	CTG Cardiomed CRO Simona Picicvnic E-mail: simona.picicvnic@ctgcro.com	Can-Fite BioPharma, Ltd., Israel	internaţional	A Phase 3, Randomized, Double-Blind, Active- and Placebo controlled, Parallel-group Trial to Evaluate the Efficacy and Safety of CF101 Compared to Methotrexate in the Treatment of Early Rheumatoid Arthritis	III	144						
667	**BPR-CS-008, version 5.0, dated 31.05.2017**	2017-001605-32	Zevtera® (ceftobiprole)	vancomycin aztreonam	Da	Infecţii bacteriene şi micoze	PSI Pharma Support Romania SRL Mihaela David E-mail: mihaela.david@psi-cro.com	Basilea Pharmaceutica International Ltd., Elveţia	internaţional	A randomized, double-blind, multicenter study to establish the safety and efficacy of ceftobiprole medocaril compared with vancomycin plus aztreonam in the treatment of acute bacterial skin and skin structure infections	III	66						
668	**HZA107116, version Final, dated 22.06.2017**	2016-004086-87	fluticasone furoate/vilanterol trifenatate Relvar Ellipta® (fluticasone furoate/vilanterol trifenatate)	fluticasone furoate	Nu	Afecţiuni ale tractului respirator	PAREXEL International Romania s.r.l. Andrei Cojocaru E-mail: andrei.cojocaru@PAREXEL.com	GlaxoSmithKline Research & Development Limited, UK	internaţional	A randomized, double-blind, parallel group, multicenter, stratified, study evaluating the efficacy and safety of once daily fluticasone furoate/vilanterol inhalation powder compared to once daily fluticasone furoate inhalation powder in the treatment of asthma in participants aged 5 to 17 years old (inclusive) currently uncontrolled on inhaled corticosteroids	III	35						
669	**NOAH-AFNET 6, Amended, dated 06.05.2016**	2015-003997-33	Lixiana® (edoxaban tosylate)	ASS Hexal® (acetylsalicylic acid)	Da	Afecţiuni cardiovasculare	The Clinical Research Institute GmbH Andrea Hüning E-mail: noah@cri-muc.eu	Kompetenznetz Vorhofflimmern e.V. (AFNET) [Atrial Fibrillation NETwork], Germania	internaţional	Non-vitamin K antagonist Oral anticoagulants in patients with Atrial High rate episodes	III	155						
670	**20160275, Amendment 2, dated 09.06.2017 VHP2017085**	2016-003554-33	Kyprolis® (Carfilzomib Lyophilisate for Solution for Injection, PR-171) Darzalex® (daratumumab)	Nu	Da	Afecţiuni oncologice	Amgen Romania SRL Daniela Stanciu E-mail: daniela.stanciu@amgen.com	Amgen Inc., USA	internaţional	A Randomized, Open-label, Phase 3 Study Comparing Carfilzomib, Dexamethasone, and Daratumumab to Carfilzomib and Dexamethasone for the treatment of Patients With Relapsed or Refractory Multiple Myeloma	III	30						
671	**RAAINBOW, version 1.0, dated 04.07.2017**	2016-003208-30	LH-8	Nu	Da	Afecţiuni ale pielii şi ţesutului conjunctiv	S.C. Scope International S.R.L. Tudor Mitu E-mail: tmitu@scope-international.com	Legacy Healthcare (France) SAS, Franţa	internaţional	Double-blind, vehicle-controlled, randomized, multi-centre study to evaluate the efficacy and safety of LH-8 cutaneous solution in children and adolescents with moderate to severe scalp alopecia areata	II/III	50						