Nr. crt.	Cod protocol	Numar EudraCT	Medicament de investigatie clinica testat	Medicament de investigatie clinica comparator	Placebo	Aria terapeutică	Sponsor	International/ national	Denumirea studiului (s-a pastrat denumirea originala - in limba engleza)	Faza	Nr. estimat de pacienti pentru Romania	Data autorizarii studiului clinic de catre ANMDM	Data opiniei CNBMDM	Data inceperii studiului	Inchidere studiu la nivel global/ Romania
1	**AB12009 RESPINS**	2012-005586-13	Masitinib	NU	DA	COPD	AB Science, France	multicentric	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	7/19/2019			
2	**AB12005 RESPINS**	2013-002293-41	Masitinib + Gemcitabine or Placebo + Gemcitabine	Masitinib + Folfiri 3 or placebo + Folfiri 3	DA	Afecţiuni oncologice	AB Science, France	multicentric	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	7/19/2019			
3	**AB12004 RESPINS**	2013-004162-34	Masitinib + Gemcitabine or Placebo + Gemcitabine	Masitinib + Folfiri 3 or placebo + Folfiri 3	DA	Afecţiuni oncologice	AB Science, France	multicentric	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	80	7/19/2019			
4	**AB12003 RESPINS**	2013-000809-23	Masitinib +docetaxel or placebo +docetaxel	NU	DA	Afecţiuni oncologice	AB Science, France	multicentric	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	7/19/2019			
5	**AB14001 RESPINS**	2014-000977-38	Masitinib	Placebo	DA	Afectiuni ale tractului respirator	AB Science, France	multicentric	A prospective, multicenter, randomised, double-blind, placebo-controlled, phase 3 study to compare the efficacy and the safety of masitinib versus placebo in the treatment of patients with severe uncontrolled asthma and elevated eosinophil levels	III	35	7/19/2019			
6	**CLCZ696B2319**	2015-004207-22	LCZ696	Enalapril	DA	Afectiuni cardiovasculare	Novartis Pharma Services AG, Switzerland	multicentric	Multicenter, open-label, study to evaluate safety, tolerability, pharmacokinetics and, pharmacodynamics of LCZ696 followed by a 52-week randomized, double-blind, parallel group, active-controlled study to evaluate the efficacy and safety of LCZ696 compared with enalapril in pediatric patients from1 month to < 18 years of age with heart failure due to systemic left ventricle systolic dysfunction	II/III	4	7/19/2019			
7	**M16-067**	2016-004677-40	Risankizumab	NU	DA	Afecţiuni ale sistemului digestiv	AbbVie Deutschland GmbH& Co. KG,	multicentric	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study to Evaluate the Efficacy and Safety of Risankizumab in Subjects with Moderately to Severely Active Ulcerative Colitis Who Have Failed Prior Biologic Therapy	II/III	35	7/19/2019	**11/15/2018**		
8	**M16-066**	2016-004676-22	M16-067	NU	DA	Afectiuni ale sistemului digestiv	AbbVie Deutschland GmbH& Co. KG, Germany	multicentric	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 Ulcerative Colitis Who Responded to Induction Treatment in M16-067 or M16-065	III	40	7/19/2019	**11/15/2018**		
9	**EIG-LNF-011**	2018-003167-54	Lonafarnib/ Ritonavir	PEG IFNalfa-2a	DA	Afectiuni ale sistemului digestiv	Eiger BioPharmaceuticals, Inc.,USA	multicentric	A Phase 3, Matrix Design, Partially Double-Blind, Randomized Study of the Efficacy and Safety of 50 mg Lonafarnib/100 mg Ritonavir BID with and without 180 mcg PEG IFN-alfa-2a for 48 Weeks Compared with PEG IFN-alfa-2a Monotherapy and Placebo Treatment in Patients Chronically Infected with Hepatitis Delta Virus Being Maintained on Anti-HBV Nucleos(t)ide Therapy (D-LIVR)	III	0	7/19/2019			
10	**LPS15017**	2017-003370-13	IGlarLixi Glargine/Lixisenatide	Premixed Insulin	NU	Boli de nutritie si metabolice	Sanofi-Aventis Groupe, France	multicentric	A multi-center open-label parallel group randomized controlled trial to compare iGlarLixi versus premixed insulin in patients with type 2 diabetes who have failed to achieve glycemic control with basal insulin and oral antidiabetic agents	III	40	7/19/2019	**12/17/2018**		

11	**CQGE031C2303**	2018-000840-24	QGE031	NU	DA	Afecţiuni ale tractului respirator	Novartis Pharma Services AG, Switzerland	multicentric	A multi-center, randomized, double-blind, active and placebo-controlled study to investigate the efficacy and safety of ligelizumab (QGE031) in the treatment of Chronic Spontaneous Urticaria (CSU) in adolescents and adults inadequately controlled with H1-antihistamines	III	28	7/19/2019	**11/6/2018**		
12	**TRCA-303**	2018-001303-36	TRC101	NU	DA	Boli de nutritie si metabolice	Tricida Inc., USA	multicentric	A Phase 3b, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of TRC101 in Delaying Chronic Kidney Disease Progression in Subjects with Metabolic Acidosis	III	250	7/19/2019	**1/8/2019**		
13	**CACZ885U2301**	2018-001547-32	Pembrolizumab plus Platinum	NU	DA	Afecţiuni oncologice	Novartis Pharma Services AG, Switzerland	multicentric	A randomized, double-blind, placebo-controlled, phase III study evaluating the efficacy and safety of pembrolizumab plus platinum-based doublet chemotherapy with or without canakinumab as first line therapy for locally advanced or metastatic non-squamous and squamous non-small cell lung cancer subjects (CANOPY-1)	III	500	7/19/2019	**6/4/2019**		
14	**3151-201-008**	2018-001605-93	Brazikumab	NU	DA	Afecţiuni ale sistemului digestiv	Allergan Ltd., UK	multicentric	A 54-Week Treatment, Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo and Active-Controlled, Parallel-Group Phase 2 Study to Assess the Efficacy and Safety of Brazikumab in Participants with Moderately to Severely Active Ulcerative Colitis	II	8	7/17/2019			
15	**01-18/629-15**	2018-003436-74	Flouracil 5 %	NU	DA	Afecţiuni ale pielii şi ţesutului conjunctiv	Intas Pharmaceuticals Ltd., India	multicentric	A Randomized, Double-Blind, Placebo-controlled, Three-arm, Parallel Assignment, Multi-Centre, Therapeutic Equivalence Study of Two Fluorouracil 5% Topical Cream Formulations in Adult Patients with Multiple Actinic Keratoses Lesions	III	130	7/19/2019	**5/30/2019**		
16	**HEP 201**	2018-004449-18	HepaStem	NU	NU	Afecţiuni ale sistemului digestiv	Promethera Biosciences, Belgium	multicentric	Multicenter, open-label, safety and tolerability study of ascending doses of HepaStem in patients with cirrhotic and pre-cirrhotic non-alcoholic steato-hepatitis (NASH)	II	15	7/31/2019			
17	**INCB 39110-210**	2018-004491-35	Itacitinib	NU	DA	Afecţiuni ale sistemului digestiv	Incyte Corporation, USA	multicentric	A Phase 2, Double-Blind, Dose-Ranging, Placebo-Controlled Study With Open-Label Extension to Evaluate the Safety and Efficacy of Itacitinib in Moderate to Severe Ulcerative Colitis	II	6	7/31/2019			
18	**MYR204**	2019-001485-15	Bulevartide & Pegylated Interferon Alfa 2A	NU	NU	Afecţiuni ale sistemului digestiv	MYR GmbH, Germany	multicentric	A Multicenter, Open-label, Randomized Phase 2b Clinical Study to Assess Efficacy and Safety of Bulevirtide in Combination with Pegylated Interferon alfa-2a in Patients with Chronic Hepatitis Delta	II	4	7/19/2019	**7/25/2019**		
19	**KPASES 02/2016**		Amlessa	NU	DA	Afectiuni cardiovasculare	S.C. KRKA Romania S.R.L	multicentric	Studiu observațional, multicentric, prospectiv, non-intervențional, care evaluează influența asocierii factorilor de risc cardio-vascular asupra reducerii tensiunii arteriale la pacienți cu hipertensiune arterială esențială tratați in mod obisnuit cu combinația in doză fixă de perindopril și amlodipină (AMLESSA®) in practica medicală curentă din România	non-interventional		7/19/2019	**2/26/2018**		