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	Inchidere temporara
1	**SHP647-301**	2017-000599-27	SHP647	Nu	Da	Afecţiuni ale sistemului digestiv	Shire Human Genetic Therapies, Inc., SUA	multicentric	A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Efficacy and Safety Study of SHP647 as Induction Therapy in Subjects with Moderate to Severe Ulcerative Colitis (FIGARO UC 301)	III	32	**5/2/2019**	**3/19/2018**			
2	**SHP647-303**	2017-000573-37	SHP647	Nu	Da	Afecţiuni ale sistemului digestiv	Shire Human Genetic Therapies, Inc., SUA	multicentric	A Phase 3 Randomized, Double-blind, Placebo controlled, Parallel group Efficacy and Safety Study of SHP647 as Maintenance Therapy in Subjects With Moderate to Severe Ulcerative Colitis (FIGARO UC 303)	III	15	**5/2/2019**	**3/19/2019**			
3	**M14-433**	2017-001240-35	Upadacitinib ABT-494	Nu	Da	Afecţiuni ale sistemului digestiv	AbbVie Deutschland GmbH & Co. KG, Germania	multicentric	A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Conventional Therapies but Have Not Failed Biologic Therapy	III	12	**5/23/2019**				
4	**M14-430**	2017-001225-41	Upadacitinib ABT-494	Nu	Da	Afecţiuni ale sistemului digestiv	AbbVie Deutschland GmbH & Co. KG, Germania	multicentric	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease who Completed the Studies M14-431 or M14-433	III	24	**5/23/2019**				
5	**M14-431**	2017-001226-18	Upadacitinib ABT-494	Nu	Da	Afecţiuni ale sistemului digestiv	AbbVie Deutschland GmbH & Co. KG, Germania	multicentric	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Induction Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Moderately to Severely Active Crohn's Disease Who Have Inadequately Responded to or are Intolerant to Biologic Therapy	III	12	**5/23/2019**				
6	**REDIV/002/17**	2017-002708-28	Rifaximin EIR	Nu	Nu	Afecţiuni ale sistemului digestiv	Alfasigma S.p.a, Italia	multicentric	Rifaximin delayed release (400 mg tablet) for the prevention of recurrent acute diverticulitis and diverticular complications. A phase II, multicenter, double-blind, placebo-controlled, randomized clinical trial (The ROAD trial)	II	64	**5/10/2019**	**12/13/2018**			
7	**CPKC412A2408**	2016-004440-12	Midostaurin (PKC412)	Nu	Nu	Afectiuni oncologice	Novartis Pharma AG, Elveția	unicentric	An open-label, multi–center, Phase IIIb study to assess the safety and efficacy of midostaurin (PKC412) in patients 18 years of age or older with newly-diagnosed FLT3-mutated Acute Myeloid Leukemia (AML) who are eligible for “7+3” or “5+2” chemotherapy schimbat prin adresa 671C/23.05.2018 An open-label, multicenter, Phase IIIb study to assess the safety and efficacy of midostaurin (PKC412) in patients 18 years of age or older with newly-diagnosed FLT3-mutated Acute Myeloid Leukemia who are eligible for “7+3” or “5+2” chemotherapy	III	15	**5/27/2019**				
8	**C3601002**	2017-002742-68	Aztreonam-Avibactam (ATM-AVI) ±Metronidazole (MTZ)	Meropenem±Colistin (MER±COL)	Nu	Infectii bateriene	Pfizer Inc., SUA	multicentric	A Phase 3 Prospective, Randomized, Multicenter, Open-Label, Central Assessor-Blinded, Parallel Group, Comparative Study to Determine the Efficacy, Safety and Tolerability of Aztreonam-Avibactam (ATM-AVI) ±Metronidazole (MTZ) versus Meropenem±Colistin (MER±COL) for the Treatment of Serious Infections due to Gram-Negative Bacteria, Including Metallo-B-Lactamase (MBL) – Producing Multidrug Resistant Pathogens, for Which There Are Limited or No Treatment Options	III	10	**5/31/2019**				

9	**IG1405**	2016-004489-24	Fibrin Sealant Grifols	Evicel	nu	Afecțiuni limfatice și ale sângelui	Instituto Grifols, S.A, Spania	multicentric	A Prospective, Randomised, Active-Controlled, Single-blind, Parallel Group Clinical Trial to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Haemostasis during Surgery in Paediatric Subjects	III	52	**5/8/2019**				
10	**CL3-05682-109**	2017-003633-28	Micronized purified flavonoid fraction 1000 mg/ chawble tablet	Micronized Purified Flavonoid Fraction 500 mg/ tablet	Nu	Afecțiuni limfatice și ale sângelui	Institut de Recherches Internationales SERVIER (I.R.I.S.), Franța	multicentric	Clinical non-inferiority study between Micronized purified flavonoid fraction 1000 mg, one chewable tablet per day and Micronized Purified Flavonoid Fraction 500 mg, 2 tablets daily after eight weeks of treatment in patients suffering from symptomatic Chronic Venous Disease (CVD). International, multicenter, double-blind, randomized, parallel group study	III	64	**5/31/2019**	**12/4/2018**			
11	**OP-103**	2016-003517-95	Melflufen/ Dexamethasone	Pomalidomide/Dexamethasone	Nu	Afecțiuni oncologice	Oncopeptides AB, Suedia	unicentric	A Randomized, Controlled, Open-Label, Phase 3 Study of Melflufen/Dexamethasone Compared with Pomalidomide/Dexamethasone for Patients with Relapsed Refractory Multiple Myeloma who are Refractory to Lenalidomide	III	10	**5/31/2019**	**9/6/2018**			
12	**NN9535-4386**	2017-003219-20	Semaglutide	Insulin Aspart	Nu	Afecțiuni nutriționale și metabolice	Novo Nordisk A/S, Danemarca	multicentric	Effect of semaglutide once-weekly versus insulin aspart three times daily, both as add on to metformin and optimised insulin glargine (U100) in subjects with type 2 diabetes	III	50	**5/27/2019**	**10/11/2018**			
13	**BR.31**	2014-004946-83	MEDI4736	Nu	Da	Afecțiuni oncologice	Clinipace GLobal Ltd., UK	multicentric	A phase III prospective double blind placebo controlled randomized study of adjuvant MEDI4736 in completely resected non-small cell lung cancer	III	15	**5/15/2019**				
14	**SB12-3003**	2018-002857-31	SB12 (biosimilar eculizumab)	Soliris®	Nu	Afecțiuni limfatice și ale sângelui	Samsung Bioepis Co., Ltd., Korea	multicentric	A Phase III Randomised, Double-blind, Multicentre Study to Compare the Efficacy, Safety, Pharmacokinetics, and Immunogenicity between SB12 (proposed eculizumab biosimilar) and Soliris® in Subjects with Paroxysmal Nocturnal Haemoglobinuria	III	10	**5/31/2019**				
15	**I8F-MC-GPGH(a)**	2018-003422-84	Tirzepatide LY3298176	Insulin Degludec	Nu	Afecțiuni nutriționale și metabolice	Eli Lilly and Company, SUA	multicentric	A Randomized, Phase 3, Open-Label Trial Comparing the Effect of LY3298176 versus Titrated Insulin Degludec on Glycemic Control in Patients with Type 2 Diabetes (SURPASS-3)	III	250	**5/2/2019**				
16	**AC-055G203**	2018-001603-37	Macitentan / ACT-064992	Nu	Nu	Afecțiuni cardiovasculare	Actelion Pharmaceuticals Ltd., Elvetia	multicentric	A long-term, multicenter, single-arm, open-label extension of the SERENADE study, to assess the safety and efficacy of macitentan in subjects with heart failure with preserved ejection fraction and pulmonary vascular disease	II	15	**5/23/2019**				