Permission given for clinical trial (r-DNA based Drug Product) (January 2014 to February 2015)

S. No.	Name of the Firm	Name of the Firm	Title of the Proposal	Date of approval
1.	M/s Roche Products India Private Limited	Rituximab	An Open-Label, Prospective, Post Marketing study, to evaluate the safety, tolerability and efficacy of Rituximab with Glucocorticoids in adults patients with wegerner'sGranulomatosis (Granulomatosis with Polyangitis-GPA) or microscopic Polyangitis vide protocol No. ML28550, Version 3.0, dated 20.05.2013.	10-Jan-2014
2.	M/s Lupin limited	Etanercept	An Open Label, Balanced, Randomized, Single-Dose, Two-Treatment, Two-Sequence, Two-Period,Crossover, Comparative Pharmacokinetics-Pharmacodynamics Study of Etanercept 50 mg Solutionfor Injection in Prefilled Syringes for Subcutaneous Injection Manufactured by Lupin Limited, Indiaand Enbrel® (Etanercept 50 mg) Solution for Injection in Prefilled Syringes for SubcutaneousInjection Manufactured by John Wyeth and Brother Ltd., UK in Healthy, Adult, Human MaleSubjects vide protocol No.LBC-P-020-13, version 02, dated 15th July 2013	30-Jan-2014
3.	M/s GSKPharmaceuticals Ltd	Panitumumab	An Open Label, multicenters, non-comparative, Phase IV study of Panituzumab to characterize its safety, tolerability, and activity in Indian Subjects with previously treated Wild type RAS (KRAS and NRAS) metastatic colorectal cancer vide protocol No. 2013N159455_00, dated 14th June, 2013	10-Feb-2014
4.	M/s Cadila Healthcare	Trastuzumab	A prospective, randomized, multi-centric, clinical study to compareTrastuzumab (Test Product, Zydus) with Trastuzumab (Reference Product, Roche /Genentech) in	10-Mar-2014

			patients with metastatic breast cancer vide TRA.12.001.01.PROT, version 1.0, dated 21st Sep, 2012	
5.	M/s Virchow Biotech Pvt. Ltd.	Peg Interferon alpha 2b	Efficacy and safety of PEG-Inferon (peginterferon alpha-2b) for the treatment of chronic hepatitis C - An open-label, multicentre study in India vide Protocol No. VB021/2012, Version 1.0 , dated 20th March 2012	9-May-2014
6.	M/s Dr. Reddy Laboratories Ltd.	Rituximab	Phase I/II clinical trial entitled "A Double-blind, randomized, parallel group study comparing the Pharmacokientics, Pharmacodynamics, Safety, Efficacy and Immunogenicity of Three Anti-CD20 Monoclonal Antibodies in patients with Moderate to severe Active, seropositive Rheumatoid Arthritis with an Inadequate Response to Methotrexate Based Therapy" vide Protocol No. RI-01-003 Amendment 1 dated 18 February 2014 (Version 2.0)	4-Jun-2014
7.	M/s Bharat Serum & Vaccines Ltd	Recombinant HCG	A prospective, multicenter, randomized, open, clinical trial to compare clinical equivalence of two brands of Recombinant Human Chorionic Gonadotropin for inducing final follicular maturation in intrauterine insemination cycles Protocol No. BSV/r-hCG/10, version 2.0, dated 23rd November 2011	4-Jun-2014
8.	M/s Novartis Healthcare	Ranibizumab (DME)	Phase IV study entitled "Unveil DME: A multi-center, open-label, observational study to evaluate the efficacy and safety of intravitreal injections (IVI) of Lucentis (Ranibizumab) in patients with visual impairment due to Diabetic Macular Edema (DME) vide Protocol No. CRFB002DIN03 Final Version No 1.0 dated 08 May 2013	4-Jul-2014
9.	M/s Novo Nordisk	Insulin degludec	A Multi-centre, prospective, open-label, single-arm, non-interventional, post marketing surveillance (PMS) study of Tresiba (Insulin Degludec) to evaluate long term safety and efficacy in patients with diabetes mellitus in routine clinical practice in India" vide Protocol No. NN1250-	14-Jul-2014

			4129, Version 1.0 dated 29/07/2013	
10.	M/s lupin limited	Peginterferonalfa 2b	An Open Label, Balanced, Randomized, Single-Dose, Two-Treatment, Two-Period Crossover Comparative Pharmacokinetics-Pharmacodynamics (PK-PD) Study of Peginterferon alfa-2b 1mcg/kg manufactured by Lupin Limited, India and ViraferonPeg® (Peginterferon alfa-2b 1 mcg/kg) manufactured by Schering Plough (Brinny) Company, Innishannon, Co. Cork, Ireland administered as Subcutaneous Injection in Healthy, Adult, Human Male Subjects vide Protocol no. LBC-P-034-13, Version: 01 dated 27thSep 2013.	18-Jul-2014
11.	M/s Biocon Pvt. Ltd.	Bevacizumab (Bmab-100)	A Double Blind, Randomized, Active Controlled, Parallel Design, Comparative PK, Efficacy, Safety and Immunogenicity Study of Bmab-100 and Avastin®, both in Combination with XELOX Chemotherapy in Patients with Metastatic Colorectal Cancer vide Protocol No BM100-CC-03-I-01, Version 1.0 dated 31 Dec 2012	7-Aug-2014
12.	M/s Bharat Serum & Vaccines Ltd	Foligraf	Immunogenicity safety (Phase IV) of Foligraf (Recombinant Human Follicle Stimulating Hormone) in subjects undergoing Assisted Reproductive Techniques vides Protocol No. BSV/r-FSH-IMG-2012 Version 01 dated 22/04/2013	11-Aug-2014
13.	M/s Novartis Healthcare	Ranibizumab (RVO)	Phase IV study entitled “An observational, multi-center, open, study assessing the efficacy and safety of Lucentis (Ranibizumabintravitreal injections) in patients with visual impairment due to Macular Edema secondary to retinal vein occlusion (RVO)” vide Protocol No. CRFB002EIN01 Version No 1.0 dated 14Jun 2012	11-Aug-2014
14.	M/s Reliance life science	Cetuximab	A Prospective, multi centric, randomized open label, two arm, parallel group, active control, comparative clinical study to evaluate efficacy, safety and pharmacokinetics	21-Aug-2014

			of R-TPR-033/ERBITUX® in patients with recurrent locoregional or metastatic squamous cell carcinoma of the head and neck videProtocol # RLS/ONC/2013/04, Version # 2.0 dated 24/03/2014	
15.	M/s Reliance life science	Pegfilgrastim	Prospective, multi-centric, open label, two arm, parallel group, active control, randomized, comparative clinical study to evaluate efficacy and safety of *R-TPR-029 / Neulasta*® when given subcutaneously in patients with Chemotherapy Induced Neutropenia" Protocol # RLS/TP/2011/01, Version 05 dated 24th Mar 2014	21-Aug-14
16.	M/s Virchow Biotech Pvt. Ltd.	Biochaperon BB PDGF	A Phase I/II, Multicentre, randomized, controlled and open-label trial comparing the efficacy and safety of two dose regimens BioChaperone PDGF-BB(Spray formulation r-Hu-PDGF-BB) to becaplermin gel for the treatment of diabetic foot ulcer vide Protocol no. BC-1CT1, Version VF2 dated 6th Aug, 2009	22-Aug-2014
17.	M/s Roche Products India Private Limited	Bevacizumab	Post Marketing Surveillance (PMS) study titled "An Indian multicentric open label prospective post marketing surveillance study of bevacizumab in the front line management of advance/metastatic epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer in real-life clinical practice vide Protocol No. ML28446 Version 1.0 dated 26/11/2012	22-Aug-2014
18.	m/s lupin limited	Rituximab	A Randomized, open-label, parallel group, active controlled Pharmacokinetic-Pharmacodynamic study with single dose of Lupin's Rituximab and Roche's Rituximab in Patients with Rheumatoid Arthritis vide Protocol No. LRP/RTX/2013/002 Version No. 1.0 dated 18th Dec 2013	26-Aug-2014
19.	M/s Intas Pharmaceutical Ltd.	Bevacizumab	A Prospective, comparative, Open label, randomized, Multicentric, Phase III study to compare the safety and	27-Aug-2014

			efficacy of Bevacizumab of Intas Pharmaceuticals Ltd against Avastin in patients with Unresectable or Metastatic Non-Squamous Non-Small Cell Lung Cancer Vide Protocol Number:476-13,Version Number 02 Dated 10TH Mar, 2014	
20.	M/s Reliance life science	Somatropin	Prospective, multicentric, randomized, open-label, two arm, parallel group, active control, comparative clinical study to evaluate efficacy, safety, Pharmacodynamics and pharmacokinetics of R-TPR-007/Norditropin (Nordilet) in growth hormone-deficient children vide Protocol # RLS/TP/2012/02, Version 2.0 dated 7th March 2014	3-Sep-2014
21.	M/s Sun Pharmaceuticals Industries Ltd	Glucagon Hypokit (r-DNA origin)	Bioequivalence study entitled "A randomized, open-label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Glucagon (Synthetic origin) 1mg injection of Sun Pharmaceutical Industries Ltd, India and Glucagon Hypokit (r-DNA origin) 1 mg injection of Novo Nordisk Inc., in 80 Human Adult subjects" vide Protocol No. GLG_1I_3572_12 Version 01 dated 04/02/2014, Amendment No. 00 dated 04/02/2014	11-Sep-2014
22.	M/s Sun Pharmaceuticals Industries Ltd	Teriparatide	A randomized, open label, two treatment, two period, two sequence, single dose, crossover, bioequivalence study of Teriparatide (synthetic origin) injection 250 mcg/ml of Sun pharmaceutical Industries limited India and Forteo (Teriparatide (rDNA origin) injection 250 mcg/ml of M/s Elililly and company limited in 60 healthy adult subjects under fasting conditions vide Protocol No: TPD_250I_3939_13 Version No 00 dated 08/08/2013	31-Dec-2014

23.	M/s Accutest Research Ltd.	Recombinant Human Growth Hormone	A comparative Pharmacokinetics and Pharmacodynamics study of subcutaneous dose of recombinant human growth hormone (r-hGH) of CristaliaProdutosQuimicosFarmaceuticosLtda (each mL containing 5.33mg of Somatropin(16IU) with Genotropin of Laboratories Pfizer Ltda. (each mL containing 5.3mg of Somatropin(16IU) through a Randomized, Open label, balanced, Two-Treatment, Two-period, Two-sequence, Single dose, Crossover study in Normal, Healthy adult male and female human subjects Under Fed condition" vide Study Code: ARL/14/047 Version No: 01	17-Dec-2014
24.	M/s Intas Pharmaceuticals Limited	Teriparatide (recombinant human Parathyroid)	An Open label, balanced, randomized, two treatment, two period, two sequence, single-dose, crossover, comparative, pharmacokinetic study of INTG8 of Intas Pharmaceuticals Limited, India to Forteo (Lilly USA, LLC) in healthy postmenopausal women after subcutaneous administration vide Protocol # 155-14, Version 01 dated 27 Mar 2014	15-Jan-2015
25.	M/s Intas Pharmaceuticals Limited	Teriparatide (recombinant human Parathyroid)	An Open label, balanced, randomized, two treatment, two period, two sequence, single-dose, crossover, comparative, pharmacokinetic study of INTG8 of Intas Pharmaceuticals Limited, India to Forsteo (Eli Lilly Nederland B.V., The Netherlands) in healthy postmenopausal women after subcutaneous administration" vide Protocol # 156-14, Version 01 dated 28 Mar 2014	2-Jan-2015
26.	M/s Intas Pharmaceuticals Limited	Rituximab concentrate for solution for infusion 500 mg/50 mL Vial	A multicentric, randomized, open label, parallel, comparative, two arms, pharmacokinetic, safety and efficacy study of INTG12 500mg/50ml concentrate for solution for infusion (Intas Pharmaceuticals Ltd, India) in comparison with Reference Medicinal Products Mabthera (Rituximab-Roche) 500mg/50ml concentrate for solution for infusion in patients with Rheumatoid	8-Jan-2015

			Arthritis vide Protocol # 163-14, Version 01 dated 21 Mar 2014	
27.	M/s Intas Pharmaceuticals Limited	Rituximab concentrate for solution for infusion 100 mg/10mL and 500 mg/50 mL Vial	A multicentric, randomized, open label, parallel, comparative, two arms, pharmacokinetic, safety and tolerability study of INTG12 100 mg/10 mL and 500 mg/50 mL concentrate for solution for infusion (Intas Pharmaceuticals Ltd., India) in comparison with Reference Medicinal Product Mabthera® (Rituximab - Roche) 100 mg/10 mL and 500 mg/50 mL concentrate for solution for infusion in patients with Non-Hodgkin's Lymphoma vide Protocol No. 151-14, Version 01 Dated 21 March 2014	8-Jan-2015
28.	M/s Intas Pharmaceuticals Limited	Pegfilgrastim	An open label, balanced, randomized, two-treatment, two period, single-dose, crossover, comparative subcutaneous pharmacokinetic and pharmacodynamic study of INTP5 of Intas Pharmaceuticals Ltd., India with Neulasta of Amgen (EU Licensed Product) in Healthy, Normal adult human subjects under fasting condition vide Protocol No. 154-14, Version 01 Dated 18 March 2014	8-Jan-2015