

List of rDNA Clinical trials to be Inspected as per the Central Inspection Plan-2019

Sr. No	Title and protocol No.
1	<p style="text-align: center;">Protocol No.: 20170199, Version 1, dated 16.08.2017</p> <p>A Multicenter, Open-label, Single-arm, Study to Evaluate Safety and Tolerability of Repatha in Patients with Homozygous Familial Hypercholesterolemia (HoFH) in India</p>
2	<p style="text-align: center;">Protocol No.: BCD-057-2, Version No. 1.1 dated 26.10.2017</p> <p>A multicenter, Comparative, randomized, Double Blind study of the Efficacy and Safety of BCD-057 (Adalimumab, CJSC BIOCAD, Russia) and Humira (Adalimumab) in patients with moderate to severe Plaque Psoriasis</p>
3	<p style="text-align: center;">Protocol No.: INSLIL08556, version no. 1.1 dated 25-Sep-2017</p> <p>A randomized, 24 week, controlled, open label, parallel arm, multicenter study comparing the efficacy and safety of the Insulin Glargine/Lixisenatide fixed ratio combination to Insulin Glargine in type 2 diabetes patients, inadequately controlled on Basal Insulin with or without Metformin</p>
4	<p style="text-align: center;">Protocol No.: TDM1.17.001.01.PROT, Version No. 1.0 dated 04.05.2017</p> <p>A prospective, randomized, multicenter, comparative, open label, parallel study to evaluate the efficacy, safety and pharmacokinetic, of test –trastuzumab emtansine (ZRC-3256; cadila healthcare Ltd) and reference –Trastuzumab emtansine (Kadcyla, Roche products (India) Pvt. Ltd.) in HER2-positive metastatic Breast Cancer patient)</p>
5	<p style="text-align: center;">Protocol No.: 1321-0023, Version 3.0 dated 23.03.2018</p> <p>Idarucizumab drug administration surveillance program: Evaluation of use of Idarucizumab in a clinical practice setting</p>
6	<p style="text-align: center;">Protocol No.: CA209887, Version No. 2.0 dated 16.11.2017</p> <p style="text-align: center;">Safety Study of Nivolumab for Advanced Malignancies in India</p>
7	<p style="text-align: center;">Protocol No.: BA1786163, Version No. 2.0 dated 29.11.2017</p> <p>A randomized, double blind, parallel, single dose of Zydus Adalimumab (ZRC-3197), injecton and HUMIRA® Adalimumab injection in healthy adult human subjects</p>
8	<p style="text-align: center;">Protocol No.: 251602, Amendment no. 2, version dated 27.09.2017</p> <p>Phase IV, Multi-Center, Prospective, Interventional, Post-marketing study in Hemophilia B patients in India receiving RIXUBIS (Coagulation Factor IX (recombinant)-250IU/Vial, 500IU/Vial, 1000IU/Vial, 2000IU/Vial and 3000IU/Vial) as on-demand or prophylaxis under standard clinical practice</p>
9	<p style="text-align: center;">Protocol No.: HCR/IV/ADALI/01/2017, version no. 1.0, dated 30.01.2017</p> <p>A Phase IV Multi-Centric Post-Marketing Study Evaluating the Safety, Immunogenicity and efficacy of the marketed formulation of Hetero-Adalimumab</p>
10	<p style="text-align: center;">Protocol No.: BM100-MI-04-I-02, version no. 3.0, dated 10.11.2017</p> <p>A multicentre open label, single arm, Phase IV clinical trial to evaluate the safety and efficacy of KRABEVA®/Abevmy™ as per the prescribing information in patient with solid tumors</p>

Sr. No	Title and protocol No.
11	<p>Protocol No.: BA1786119, Version 00, dated 18.08.2017</p> <p>A randomized, double-blind, parallel, single dose comparative pharmacokinetic study of Zydus Trastuzumab (ZRC-3114) and 'HERCEPTIN®' (Trastuzumab) in healthy, adult, male subjects</p>
12	<p>Protocol No.: ALK05-TERI1, Phase III, Version No. 02 dated 22.09.2016</p> <p>A Prospective, comparative, active controlled, randomized, open label, multicenter study to compare safety and efficacy of teriparatide of Enzene Biosciences Ltd Versus Forteo of Eli Lilly in the treatment of Postmenopausal Osteoporosis</p>
13	<p>Protocol No.: RLS/PMS/2016/07, Version 4.0 dated 06-Jul-2018</p> <p>A prospective, multi-centre, open label, Phase IV study to evaluate safety and efficacy profile of AdaliRef in patients with moderate to severe plaque psoriasis</p>
14	<p>Protocol No.: ALK12/ENZ15-DEN1, Amendment 01, Version 2.0, dated 26.10.2017</p> <p>A Prospective, Active-controlled, Randomized, Double Blind, Multicenter, Phase III study to compare the safety and efficacy of Biosimilar Denosumab of Enzene Biosciences Limited versus Innovator Denosumab in the treatment of Post menopausal Osteoporosis”, Protocol no. ALK12/ENZ15-DEN1, Amendment 01, Version 2.0, dated 26.10.2017</p>
15	<p>Protocol No.: 54767414MMY4008; Pragmatic Phase IV, dated 10.03.2017</p> <p>A prospective, single arm, Multicenter, Pragmatic Phase IV trial investigating safety and Efficacy of Darzalex (Daratumumab) in Indian Subjects with Relapse and Refractory Multiple Myeloma, whose Prior Therapy included a proteasome inhibitor and and immunomodulatory agent</p>
16	<p>Protocol No.: AU-01-002, version no. 1.0, dated 11.01.2018</p> <p>Phase 1, Blinded, Randomized, Parallel-group, Single dose, Comparative Pharmacokinetic Study of DRL_Adalimumab (DRL_AU) and Reference Adalimumab Administered by the Subcutaneous Route to Normal Healthy Male Subjects</p>
17	<p>Protocol No.: CNTO148SPD4001, dated 17.01.2018</p> <p>A Phase IV, multicenter, noncomparative, open-label study evaluating the safety and efficacy of Golimumab (a fully human anti-TNFα monoclonal antibody, administered subcutaneously) in the treatment of Indian patients with active Spondyloarthritis of Ankylosing Spondylitis (AS) and Psoriatic Arthritis (PsA)</p>
18	<p>Protocol No.: 0043-18, Version 1.0 dated 05-Mar-2018</p> <p>A prospective follow-up study to evaluate the long-term safety of Intas Denosumab in postmenopausal women and men with osteoporosis at high risk of fracture” with protocol No. 0043-18, Version 1.0 dated 05-Mar-2018</p>
19	<p>Protocol No.: USVCAP/USV/P2/001, Version 2.0, dated 14-Feb-2018.</p> <p>Phase IIb, open label, Randomized, Comparative study to Evaluate the Safety and Efficacy of USVCAP formulation in Type 2 Diabetes Mellitus Subjects Uncontrolled with Metformin Hydrochloride Treatment vide Protocol No. USVCAP/USV/P2/001, Version 2.0, dated 14-Feb-2018.</p>
20	<p>Protocol No.: 0262-17, Version No. 1.0, Protocol Date 09-MAR-2018</p> <p>A randomized, assessor-blind, two-treatment, two-period, two-way crossover, bioequivalence study of recombinant human follicle stimulating hormone (r-h-FSH) of Intas Pharmaceuticals Ltd. with Gonal-F in pituitary down-regulated healthy female subjects</p>

Sr. No	Title and protocol No.
21	<p>Protocol No.: BA1786032, Version No. 00, Protocol Date 08-MAY-2018</p> <p>A randomized, doubleblind, balanced, two-treatment, two-period, crossover, single dose pharmacokinetic and pharmacodynamic bioequivalence study of Zydus Pegfilgrastim (ZRC-3128) and 'NEULASTA®' (Pegfilgrastim) in healthy adult human subjects under fasting conditions</p>
22	<p>Protocol No.: 0446-16 Version No. 2.0 Protocol Date 03-MAY-2018</p> <p>A randomized, double-blind, three-treatment, single-dose, parallel group, bioequivalence study of biosimilar Bevacizumab of Intas Pharmaceuticals Limited, India with Avastin™ in normal adult healthy volunteers</p>
23	<p>Protocol No.: ALK10/ENZ110-ROMI1 Version 1.0 dated 10.05.2018</p> <p>A prospective, multicenter, randomized, double blind study to compare efficacy and safety of ENZ110 (similar biologic of Romiplostim) versus innovator Romiplostim in patients with chronic immune thrombocytopenia (ITP)</p>
24	<p>Protocol No.: MK-3475-593 Version No. 02 Protocol Date dated 17-MAY-2018</p> <p>A Prospective, Open-label, Phase 4 Study to Evaluate the Safety of Pembrolizumab (KEYTRUDA®) in Subjects with Unresectable or Metastatic Melanoma or PD-L1 positive Non-small Cell Lung Cancer (NSCLC) in India (Keynote-593)</p>
25	<p>Protocol No.: BGL-IA-CTP301-V1, Version No. 1 Dated 07-MAY-2018</p> <p>A Randomized, Open Label, Parallel-group, Multi-center Phase 3 Study to compare Efficacy and Safety of Recombinant Insulin Aspart (Manufactured by BioGenomics Limited) with NovoRapid® (Manufactured by Novo Nordisk), in Adult Patients with Diabetes Mellitus</p>
26	<p>Protocol No.: TZ-02-001, Version 2.0 dated 14.06.2018</p> <p>A Prospective, single arm, multicenter post marketing study Phase 4 Study to Evaluate the Safety and efficacy of Dr. Reddy's Trastuzumab (DRL-TZ) in patients with HER2-positive Cancer</p>