

cliantha[®]
research

Oncology & Biosimilars Capabilities



20

YEARS OF EXCELLENCE
IN CLINICAL RESEARCH

cliantha.com

USA | CANADA | INDIA

About Cliantha



Cliantha Research, full-service Clinical Research Organization (CRO), provides comprehensive and integrated offerings in Early Phase (BA-BE & Phase I), Late Phase (II-IV), Respiratory, Dermatology, Consumer Research, Research Lab, IVRT-IVPT, Biometrics, Medical Services, Environmental Exposure Chambers (EECs).

Cliantha, by leveraging on the depth of experience provides ethical, value added customer centric services rooted in excellence, thereby enabling clinical development of pharmaceutical, biotech & healthcare companies.

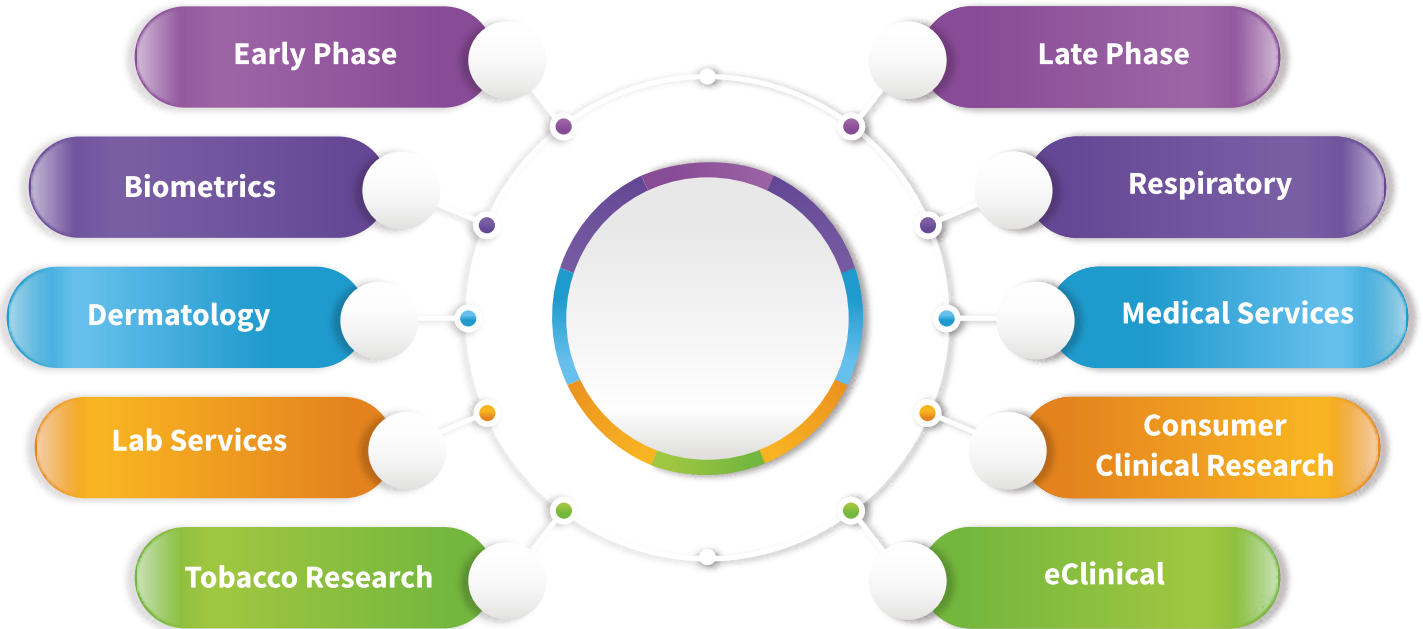
Cliantha strategically acquired Hill Top Research, Inflamm Research and Karmic Lifesciences globally to widen the horizon of clinical research & support services for end-to-end developmental needs all across. The acquired companies hold established brand equity in Dermatology, Respiratory and Data Management segments respectively with additional niche expertise in Consumer Clinical Research & Environmental Exposure Chambers (EEC) Studies.

With several advanced clinical sites and bio-analytical laboratories in North America and India, Cliantha now has presence in 3 countries along with a strong team of 1500+ professionals. Some of the key regulators, such as the USFDA, GCC, EMA, AGES, ANSM, ANVISA, AMPS, MCC South Africa, Health Canada, DCGI, CAP, NABL, Turkey MOH, Thailand MoPH, Malaysia NPRA have successfully inspected Cliantha across the globe.

Cliantha Research is headquartered in Ahmedabad and has expanded its domestic reach with 3 regional offices & has presence in USA (Florida) & Canada (Mississauga and Toronto).



Centres of Excellence



Location Specific Services



CANADA

TORONTO

Bioanalytical Lab
IVRT/IVPT Lab
Veterinary Sample Analysis

MISSISSAUGA

Early Phase (BA-BE / Phase I)
Late Phase Research
Environmental Exposure Chambers
Consumer Clinical Research

INDIA

AHMEDABAD

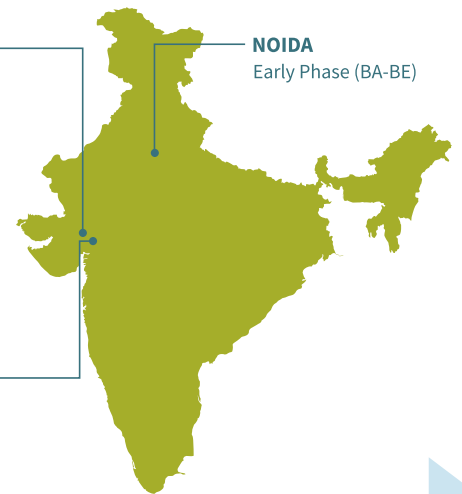
Early Phase (BA-BE / Phase I)
Late Phase Research
Consumer Clinical Research
Data Management

NOIDA

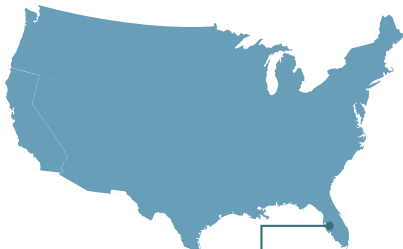
Early Phase (BA-BE)

VADODARA

Early Phase (BA-BE/Phase I)



USA



ST. PETERSBURG, FLORIDA

Early Phase (BA-BE)
Dermatology Rx Research
Consumer Clinical Research



Oncology Capabilities



225+
Early Phase
Studies

58
Late Phase
Studies

20+
Indications

725+
Sites

12700+
Subjects -
Patients

Early Phase (Pilot)

Molecule Name	Strength	Dosage Form	Regulatory	Studies	Subjects
Alectinib	150 mg	Capsule	USFDA	3	44
Asciminib	40 mg	Tablet	USFDA	2	35
Axitinib	5 mg	Tablets	USFDA	3	43
Cabozantinib	30 mg, 40 mg , 60 mg	Tablet, Capsule	USFDA	10	177
Dasatinib	50 mg, 100 mg, 140 mg	Tablet	EU, EMA, USFDA	20	349
Deucravacitinib	6 mg	Tablets	USFDA	2	30
Erlotinib	150 mg	Tablets	USFDA	8	112
Gefitinib	250 mg	Tablets	MENA	1	14
Ibrutinib	20 mg, 140 mg, 560 mg	Tablet, Capsule	USFDA	26	391
Larotrectinib	100 mg	Capsule	USFDA	3	42
Lenvatinib	10 mg	Capsule	Health Canada	2	32
Neratinib	40mg	Tablets	USFDA	1	14
Nilotinib	200mg	Capsule	EU, USFDA, Health Canada	5	92
Nintedanib	150 mg	Capsule	USFDA, TMMDA+EMA	6	88
Osimertinib	80 mg	Tablets	USFDA	2	22
Pazopanib	200mg	Tablets	USFDA, EU	6	96
Ruxolitinib	20 mg, 50 mg	Tablets	EMA, USFDA	3	44
Sunitinib	50 mg	Malate Capsule	USFDA	1	18
Tofacitinib	5mg, 10 mg, 11 mg, 22 mg	Tablets	USFDA, NMPA, MHRA	21	292
Zanubrutinib	80 mg	Capsule	USFDA	4	54

Early Phase (Pivot)

Molecule Name	Strength	Dosage Form	Regulatory	Studies	Subjects
Cabozantinib	60 mg	Tablets	USFDA, EMA	3	378
Dasatinib	20 mg, 50 mg, 100 mg, 140 mg	Tablets	EMA, USFDA, PMDA, ANVISA	20	890
Erlotinib	150 mg	Tablets	USFDA, EU, TGA, ASEAN PPWG, EMA	14	617
Ibrutinib	140 mg , 560 mg	Tablet, Capsule	USFDA	5	254
Imatinib	400 mg	Tablets	USFDA, EMA, EU, NPRA	5	186
Nilotinib	200 mg	Capsule	USFDA, ASEAN PPWG, EMA, MENA, Health Canada	8	564
Nintedanib	100 mg, 150 mg	Capsule	USFDA, EMA	10	674

Oncology Capabilities



Early Phase (Pivot)

Molecule Name	Strength	Dosage Form	Regulatory	Studies	Subjects
Osimertinib	80 mg	Tablets	USFDA	2	56
Pazopanib	200 mg, 400 mg	Tablets	EMA, EU, Health Canada	4	144
Ruxolitinib	20 mg	Tablets	EMA, Health Canada, IL MOH, NMPA	7	252
Sorafenib Neapolis	200 mg	Tablets	MENA	1	20
Sunitinib	12.5 mg	Capsule	ANVISA	2	62
Tofacitinib	5mg, 10 mg, 11 mg, 22 mg	Tablets	USFDA, EU, EMA, Health Canada, TMMDA	24	952
Trametinib	2 mg	Tablets	USFDA	1	40

Late Phase

Sr. No.	Molecule	Indication	Regulatory	Sites	Patients
1	AUR 103 Tablet	HER2-positive Advanced Gastric/ Gastroesophageal Junction	USFDA + CDSCO	22	18
2	AUR 104 Tablet	Relapsed/Refractory Lymphoid Malignancies	USFDA + CDSCO	15	42
3	AUR-107 Capsule	Multiple Myeloma	USFDA	12	20
4	AUR 109 Tablet	Colorectal, Ovarian, and Renal Cancer	USFDA	25	90
5	AUR-108 Capsule	Relapsed Advanced Lymphoma	DCGI	17	30
6	Bevacizumab 15mg/kg Injection	Metastatic Colorectal Cancer	EU	6	24
7	Bevacizumab 15mg/kg Injection	Non-small-cell Lung Carcinoma	USFDA	30	650
8	Bevacizumab 15mg/kg Injection	Metastatic Colorectal Cancer	DCGI	26	111
9	BIO-11006 125mg Inhalation Solution	Non-small-cell Lung Carcinoma	USFDA	10	60
10	BRAF testing	Metastatic/Locally Advanced NSCLC	DCGI	4	100
11	CA-170 Injection	Stage IV Non-Squamous Non-Small Cell Lung Cancer	DCGI	25	100
12	Capecitabine 500 mg Tablet	Metastatic Breast/Colorectal Cancer	USFDA + EU	10	42
13	Capecitabine 500 mg Tablet	Metastatic Breast/Colorectal Cancer	USFDA	14	54
14	Capecitabine 500 mg Tablet	Metastatic Breast/Colorectal Cancer	EU	10	46
15	Cladribine IV Injection	Hairy Cell Leukemia	Saudi Arabia	-NA-	-NA-
16	Cladribine SC Injection	Hairy Cell Leukemia	EU	-NA-	-NA-
17	Doxorubicin	Breast and Ovarian Cancer	Health Canada	10	62
18	Hu14.18K322A Injection	High-Risk Neuroblastoma	USFDA	8	80
19	Imatinib Mesylate 400mg Tablet	GIST and CML	USFDA	6	38
20	Imatinib Mesylate 600mg Tablet	GIST and CML	USFDA	8	38
21	ISB 1442	Relapsed/ Refractory Multiple Myeloma	-NA-	-NA-	-NA-

Oncology Capabilities

Late Phase

Sr. No.	Molecule	Indication	Regulatory	Sites	Patients
22	ISB 2001	Relapsed/ Refractory multiple myeloma	-NA-	-NA-	-NA-
23	Ixazomib 4mg Capsule	Multiple Myeloma	EMA	10	0
24	KSHN001126 Tablet	Hormone receptor (HR)-positive or human epidermal growth factor receptor 2 (HER2) -negative advanced breast cancer	USFDA	10	24
25	Lenvatinib 24 mg Capsule	Thyroid Cancer	DCGI	10	50
26	Leuprolide acetate 7.5mg/Vial	Prostate Carcinoma	USFDA	22	60
27	Leuprolide Acetate for Depot Suspension, 30 mg	Prostate Carcinoma	USFDA	5	30
28	Leuprolide acetate 30mg Injection	Prostate Carcinoma	USFDA	40	820
29	Nivolumab 3mg/kg IV Infusion	Advanced or Metastatic Non-Small Cell Lung Cancer	DCGI	45	248
30	Olaparib 150 mg Tablet	Ovarian Cancer	USFDA	12	48
31	Olaparib 150 mg Tablet	Cancer and Stable on Olaparib Therapy	USFDA	12	28
32	Olaparib 150 mg Tablet	ovarian cancer or breast cancer or prostate cancer under Fasting Condition	ANVISA + Canada	20	42
33	Olaparib 150 mg Tablet	ovarian cancer or breast cancer or prostate cancer under Fed Condition	ANVISA + Canada	20	42
34	Olaparib 150 mg Tablet	Ovarian or Breast Cancer	EU	15	42
35	Olaparib 150 mg Tablet	Ovarian or Breast Cancer	EU	15	42
36	Olaparib 150 mg Tablet	ovarian cancer or breast cancer or prostate cancer under Fed Condition	USFDA	25	42
37	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	USFDA	5	18
38	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	USFDA	5	14
39	Olaparib 150 mg Tablet	Her2 negative metastatic breast cancer, pancreatic adenocarcinoma and prostate carcinoma	EU	4	0
40	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	EMA	12	72
41	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	Health Canada	12	42
42	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	Health Canada	14	48
43	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	EMA	17	NA
44	Olaparib 150 mg Tablet	Ovarian, Breast, Pancreatic, and Prostate Cancer	Health Canada	12	42
45	Paclitaxel 100mg Injectable Suspension	Metastatic Breast Cancer	USFDA	21	90
46	Paclitaxel 100mg Injectable Suspension	Metastatic Breast Cancer	USFDA	5	50
47	Paclitaxel 100mg Injectable Suspension	Metastatic Breast Cancer	USFDA	6	20

Oncology Capabilities



Late Phase

Sr. No.	Molecule	Indication	Regulatory	Sites	Patients
48	Paclitaxel 100mg Injectable Suspension	Metastatic Breast Cancer	USFDA	10	90
49	Paclitaxel 100mg Injectable Suspension	Breast Cancer	USFDA	10	70
50	Paclitaxel 100mg Injectable Suspension	Metastatic Breast Cancer	USFDA	8	60
51	Rituximab Biosimilar Injection	Diffuse large B-cell lymphoma	EU	13	73
52	Sunitinib Malate 50mg Capsule	Renal Cell Carcinoma	USFDA	12	46
53	Sunitinib Malate 50mg Capsule	Renal Cell Carcinoma	USFDA	5	13
54	Thermal desorption (TD) Tubes	Oesophageal/Gastro-Oesophageal	MHRA , USFDA +	4	900
55	Trastuzumab	Junction Adenocarcinoma Metastatic Breast Cancer	CDSCO DCGI + ROW	34	102
56	Trastuzumab	Early Breast Cancer	USFDA	1	10
57	Trastuzumab	Metastatic Breast Cancer	NA	1	10
58	Trastuzumab	Metastatic breast Cancer	NA	10	20

Biosimilars Capabilities

20
Early Phase
Studies

15
Late Phase
Studies

07
Indications

250+
Sites

1250+
Patients

Early Phase

Molecule	Indication	Dosage Form	Regulatory	Subjects
Adalimumab	40 mg	Injection	EMA + USFDA + EMB	154
Bevacizumab	100 mg (25 mg/mL)	Infusion	EU	102
Darbepoetin	60/40µg	Injection	Health Canada	100
Etanercept	50 mg	Injection	USFDA	80
Filgrastim	300 mcg/0.5 ml	PFS	USFDA + Health Canada	136
Pegfilgrastim	6 mg/0.6 mL	Injectable solution	EMA + USFDA	274
Pegfilgrastim	6 mg/0.6 mL	Injectable solution	EMA + USFDA	274
Pegylated Erythropoietin	100 mcg/0.3 ml	Injection	DGDA	126
Repoitin	10000IU/mL	Injection	ROW	114

Early Phase

Molecule	Indication	Dosage Form	Regulatory	Subjects
Semaglutide	15 mg/3 mL (5mg/mL)	Injectable solution	CDSCO	220
Trastuzumab	150 mg	Powder for concentrate for solution for infusion	EU	60
Abatacept	125 mg/mL	Injection	USFDA + EMEA	300
Abatacept	125 mg/mL	Injection	USFDA + EMEA	300
Omalizumab	150 mg/mL	Injection (PFS Vs AI)	USFDA	150
Pegfilgrastim	6 mg/0.6 mL	Injection (PFS Vs AI)	USFDA	180

Late Phase

Therapeutic Area	Molecule	Indication	Regulatory	Site	Patients
Gynecology	Recombinant Human FSH	IVF	DCGI	9	116
Oncology	Rituximab	Diffuse large B-cell lymphoma	EU	13	73
	Bevacizumab	Metastatic colorectal cancer	EU	6	24
	Bevacizumab	Non-small-cell lung carcinoma	USFDA	30	650
	Bevacizumab	Metastatic colorectal cancer Advanced or Metastatic	DCGI	26	111
	Nivolumab	Non-Small Cell Lung Cancer	DCGI	45	248
	Trastuzumab	Metastatic Breast Cancer	DCGI + ROW	34	102
	Trastuzumab	Metastatic breast cancer	NA	10	-
	Trastuzumab	Early Breast Cancer	USFDA	0	0
Ophthalmology	Trastuzumab	Metastatic Breast Cancer	NA	0	0
	Aflibercept	Diabetic Macular Edema	USFDA + EU + Japan + India	15	100
	Aflibercept	Diabetic Macular Edema	USFDA + EU + Japan + India	15	65
	Aflibercept	Diabetic Macular Edema	USFDA	5	35
	Aflibercept	Diabetic Macular Edema	NA	40	184
	Ranibizumab	Neovascular Age-related Macular Degeneration	DCGI	16	152

Clinical Trial Services



Medical Services



Regulatory Affairs



Clinical Trial Feasibility



Clinical Operations



Clinical Project Management



Biometrics



Biomarkers,
Clinical &
Bioanalytical Lab



Central Monitoring



eTMF Solutions



Clinical Trial
Supply
Management



Biomarker Assay

Analyte	Matrix	Sensitivity	Assay Format
Growth Hormone	Human Serum	75.0 pg/mL	ELISA
Tissue factor pathway inhibitor (TFPI)	Human Plasma	31.25 ng/mL	ELISA
Enoxaparin Sodium Anti Factor IIa	Human Plasma	0.030 IU/mL	Chromogenic
Enoxaparin Sodium Anti Factor Xa (Chromogenic assay)	Human Plasma	0.050 IU/mL	Chromogenic
Enoxaparin sodium Anti Factor Xa (Clotting assay)	Human Plasma	0.075 IU/mL	Clot based
LMWH for APTT	Human Plasma	NA	Clot based
LMWH Anti Factor IIa	Human Plasma	0.020 IU/mL	Chromogenic
LMWH Anti Factor Xa	Human Plasma	0.040 IU/mL	Chromogenic
Hep test (LMWH by Anti-Xa)	Human Plasma	0.075 IU/mL	Clot based
Hemolytic potential of drug	Human blood	-	Chromogenic
Adiponectin	Human Serum	0.1 ug/mL	ELISA
LMWH HEP Test - EU	Human Plasma	0.100 IU/mL	Clot based
LMWH Anti Factor Xa (Chromogenic assay) - EU	Human Plasma	0.050 IU/mL	Chromogenic
LMWH Anti Factor IIa (Chromogenic assay) - EU	Human Plasma	0.030 IU/mL	Chromogenic
LMWH for APTT -EU	Human Plasma	NA	Clot based
In-Vitro Protein Flocculation	Human Plasma	NA	Chromogenic
Platelet Activation	Whole blood	NA	Flow cytometry
In-Vitro Hemolytic Index	Whole blood	0.025 mg/mL	Colorimetric
RBC Acetylcholinesterase	Whole blood	1.0 mU/mL	Colorimetric
Free IgE	Human Serum	7.810 ng/mL	ELISA
Total IgE	Human Serum	62.5 ng/mL	ELISA
CTX-I	Human Serum	0.670 ng/mL	ELISA
Classical Complement Pathway	Human Serum	-	ELISA
Alternative Complement Pathway	Human Serum	-	ELISA
Free- Properdin	Human Serum	469.0 ng/mL	ELISA
Total Properdin	Human Serum	2.580 µg/mL	ELISA
Alternative Complement Pathway Activity (ACPA) by RBC Pronase	Human Serum	-	ELISA
Absolute Neutrophil Count (ANC)	Human Whole Blood	0.03 x 103/uL	Flow cytometry method using semiconductor laser
Hemoglobin (Hb)	Human Whole Blood	0.1 g/dL	SLS-hemoglobin method
Red Blood Cell (RBC)	Human Whole Blood	0.01 x 106/µL	Hydrodynamically focused DC detection method
Hematocrit (HCT)	Human Whole Blood	0.1 %	Hydrodynamically focused DC detection method
Reticulocyte Count %	Human Whole Blood	0.00 %	Flow Cytometry method using Semiconductor Laser
Iron	Human Serum	7.00 ug/dL	CMIA
Ferritin	Human Serum	1.98 ng/mL	CMIA
CD19 %	Human Whole Blood	0.0 %	Flow Cytometry
Absolute CD19 Count	Human Whole Blood	0.0 cell / uL	Flow Cytometry

Our Team



Naveen Sharma

CEO

- 30+ years of experience
- 20+ years with Cliantha

Dr. Dharmesh Domadia

VP - Global Clinical Operations

- 20+ years of experience
- 7+ years with Cliantha

Devesh Verma

Director - Clinical Trials

- 18+ years of experience
- 8+ years with Cliantha

Hitesh Maheshwari

Associate Director - Clinical Trials

- 18+ years of experience
- 7+ years with Cliantha

Dr. Ankesh Barnwal

Director - Medical Services

- 16+ years of experience
- 15+ years with Cliantha

Sumit Dodia

Associate Director - Regulatory, Study Start-up, eTMF, CRM

- 17+ years of experience
- 8+ years with Cliantha

Dhaval Patel

Associate Director - Data Management

- 17+ years of experience
- 10+ years with Cliantha

Anshul Dogra

VP - Bioanalytical Lab

- 24+ years of experience
- 19+ years with Cliantha

Dr. Shaifali Gupta

Sr. Director - Clinical Lab

- 23+ years of experience
- 14+ years with Cliantha

Hitesh Chauhan

Associate VP - Biometrics

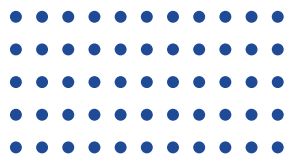
- 24+ years of experience
- 19+ years with Cliantha

Arpana Prasad

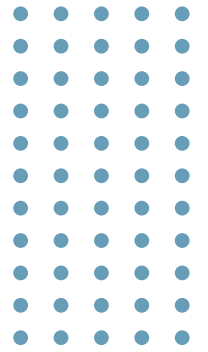
VP - Global QA/QC

- 27+ years of experience
- 20+ years with Cliantha

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cliantha[®]
research



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