18 YEARS OF EXCELLENCE IN RESEARCH

cliantha® research

RESPIRATORY

NORTH AMERICA

BE STUDIES

Type of Product	Studies
MDI	15+
DPI	10+
Intranasal	5+
Respules	5+

PHASE 1 STUDIES

Indication	Studies
Asthma	50+
COPD	20+
Allergic Rhinitis	30+
Healthy Volunteers	100+
Pediatric (adolescents)	1

CLINICAL TRIAL MANAGEMENT

Indication	Studies
Asthma	15+
COPD	20+
SAR	60+
Healthy Volunteers	NAP
Pediatric (adolescents)	3

EARLY PHASE (INDIA)

Study Name	Type	Regulatory	Subjects
ALDP 001(Single Ascending Doses (SAD)) intranasal-	Phase 1A	CDSCO & USFDA	48
Albuterol Sulfate 90 mcg per metered dose Inhalation Aerosol	Pilot	USFDA	12
		USFDA	14
		USFDA	14
		USFDA	8
Budesonide/Formoterol fumarate dihydrate 160 µg /4.5 µg inhalation		EU	27
Fluticasone Propionate 0.044 mg Aerosol		EU	36
Fluticasone Propionate HFA 220 µg per Actuation Inhalation Aerosol		USFDA	24
Indacaterol/Glycopyrronium 110mcg/50mcg inhalation powder, hard capsules		EU	18
Indacaterol/Glycopyrronium 85 mcg/43 mcg Inhalation Powder, hard Capsule		EU	14
		EMA	18
Ipratropium Bromide HFA 21µg (4 x 21 µg dose) Inhalation Aerosol		EMA	24
Methylcobalamin 500µg Nasal Spray		CDSCO	12
Olopatadine Hydrochloride 665 mcg/spray Nasal Spray		USFDA	12
Tiotropium 18 mcg/13 mcg DPI		EU & TGA	18
ALDP 001 0.125% intranasal	Pilot (Phase 0)	CDSCO & USFDA	8
Albuterol Sulfate 90 mcg Inhalation Aerosol	Pivotal	USFDA	60
Albuterol Sulfate 90 mcg per actuation Inhalation Aerosol		USFDA	78
Albuterol Sulfate 90mcg Inhalation		USFDA	20
Fluticasone Propionate 50 mcg per spray Nasal spray		USFDA	80
Ipratropium Bromide HFA 21µg Inhalation Aerosol		USFDA	78
Olopatadine Hydrochloride 665 Mcg/Spray Nasal Spray		USFDA	24
Grand Total			**647**

LATE PHASE (INDIA)

	Molecule	Regulatory	Sites	Patients
Asthma	Albuterol Sulphate	USFDA	8	20
	Budesonide & Formoterol	USFDA	12	60
	Advair	NA	4	300
Chronic Obstructive Pulmonary Disease	Revefenacin	DCGI	20	244
	Glycopyrronium and Formoterol	DCGI	14	330
	Tiotropium Bromide	USFDA	18	225
	Ipratropium Bromide	USFDA	15	120
	Tiotropium Bromide	USFDA	8	100
COVID-19	NCE	Multiple	20	200

REGULATORY EXPERIENCE - NORTH AMERICA

- We are abreast of all of the guidelines in Respiratory area
- We have worked with our clients to shorten timelines by virtue of speaking with FDA OGD with our clients to take slightly different approaches than are in the guidelines. This provides time and cost efficiencies.
- Good Safety cover is an important factor for USFDA. Inflamax proprietary electronic tablet allows close monitoring of patients during long inhalation trials where they are on placebo.
- Having at least 30% of the trial performed in NA with 70% in India.

REGULATORY EXPERIENCE - INDIA

- Team has 100+ cumulative years of experience to represent the protocols in NDAC (earlier) and SEC (now) for various therapeutic areas like Oncology, Haematology, Dermatology, Pulmonary, Ophthalmology, Cardiovascular & Renal, Endocrinology, Antibacterial, Reproductive and Urology, Neurology &Psychiatry, etc.
- More than 30 SEC deliberations in last 2 years and received Clinical Trials approval
- Our astute team has an competitive edge of detailed understanding of Scientific, Operational, Medical, Statistical and Regulatory expectations of SEC experts and DCGI members