cliantha® research

Experience that breath success into every trial.

Respiratory Clinical Trials

cliantha.com

USA | CANADA | EUROPE | INDIA

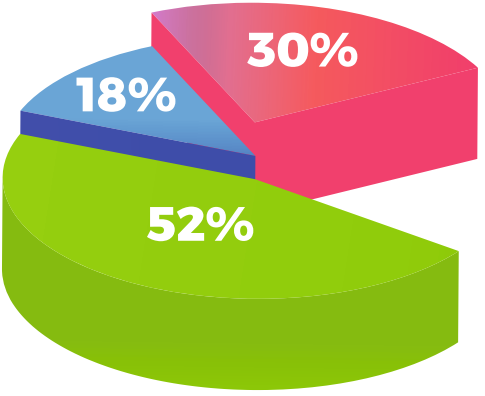
Overview

The Global Burden of Disease data suggests that respiratory diseases contribute to high morbidity and mortality and is third leading cause of death. Chronic obstructive pulmonary disease (COPD) & asthma lead this therapeutic category.

Respiratory clinical studies are complex and challenging studies. When stakes are high, you need partner with deep therapeutic & regulatory expertise.

Cliantha Research is full service global CRO with a unique approach to clinical development & is well suited to manage some of the industry's most complex and challenging Respiratory clinical studies.

RESPIRATORY EXPERIENCE



CLINICAL TRIAL MANAGEMENT

Indication	
• Asthma	• SAR
• COPD	• Healthy Volunteers
• Pediatric (adolescents)	

PHASE 1 STUDIES

Indication	
• Asthma	• Allergic Rhinitis
• COPD	• Healthy Volunteers
• Pediatric (adolescents)	

BE STUDIES

Type of Product	
• MDI	• Intranasal
• DPI	• Respules

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)

Molecule Name	Strength	Dosage Form	Regulatory	Study	Subjects
Albuterol Sulfate	90 mcg	Inhalation Aerosol	USFDA	Pilot	14
	90 mcg		USFDA	Pivotal	60
	90 mcg		USFDA	Pilot	14
	90 mcg		USFDA	Pilot	12
	90 mcg		USFDA	Pilot	8
	90 mcg		USFDA	Pivotal	20
	90 mcg		USFDA	Pivotal	42
	90 mcg		USFDA	Pivotal	36
ALDP 001	0.125%	Nasal Spray & Ophthalmic Solution	CDSCO & USFDA	Pilot (Phase 0)	8
	0.5%		CDSCO & USFDA	Pilot	12
ALDP 001(Multiple Ascending Doses (Mad))	0.25% and 0.5%		CDSCO & USFDA (Phase 1)	Pivotal	32
Aldp 001(Single Ascending Doses (Sad))	0.125%, 0.25% and 0.5%	Nasal Spray	CDSCO & USFDA (Phase 1)	Pivotal	48
Azelastine Hydrochloride and Fluticasone Propionate	137 mcg/50 mcg		USFDA	Pilot	18
	137 mcg/50 mcg		EU	Pivotal	56
Budesonide + Formoterol Fumarate Dihydrate	80 mcg/4.5 mcg	Inhalation Aerosol	USFDA	Pivotal	24
Budesonide/Formoterol Fumarate Dihydrate Dpi	160 mcg /4.5 mcg		EU	Pilot	27
Fluticasone Propionate	50 mcg	Nasal Spray	USFDA	Pivotal	70
	50 mcg		USFDA	Pivotal	80
	0.044 mg	Inhalation Aerosol	USFDA	Pilot	36
Fluticasone Propionate Hfa	220 mcg per Actuation	Inhalation Aerosol	USFDA	Pilot	24
Indacaterol/Glycopyrronium	85 mcg/43 mcg	Inhalation Powder, Hard Capsule	EMA	Pilot	18
	110 mcg/50 mcg		EU	Pilot	18
	110 mcg/50 mcg		EMA	Pilot	18
	85 mcg/43 mcg		EU	Pilot	14
	85 mcg/43 mcg		EMA	Pilot	14
	110 mcg/50 mcg		EMA	Pilot	18
Ipratropium Bromide Hfa	21 mcg (4 x 21 mcg dose)	Inhalation Aerosol	USFDA	Pilot	24
	21 mcg		USFDA	Pivotal	78
Ipratropium Bromide Mdi	20 mcg	Inhalation Solution	CANADA	Pivotal	24
Methylcobalamin	500 mcg	Nasal Spray	CDSCO	Pilot	12
Olopatadine Hydrochloride	665 mcg	Nasal Spray	USFDA	Pivotal	24
	665 mcg		USFDA	Pilot	12
Tiotropium	18 mcg/13 mcg	Inhalation Aerosol	EU/TGA	Pilot	18

LATE PHASE (INDIA)

	Molecule	Regulatory	Sites	Patients
Asthma	Albuterol Sulphate 90 mcg Inhalation Powder	USFDA	8	20
	Budesonide + Formoterol 80mcg + 4.5 mcg Aerosol	USFDA	12	60
	Fluticasone Propionate + Salmeterol 100mcg +50mcg Inhalation Powder	NA	4	300
	MyTatva application Asthma	DCGI	4	100
Chronic Obstructive Pulmonary Disease (COPD)	Revefenacin 175mcg Inhalation	DCGI	20	244
	Glycopyrronium and Formoterol 18/9.6µg Inhaler	DCGI	14	330
	Tiotropium Bromide 18 µg Inhalation Powder	USFDA	18	225
	Tiotropium Bromide 18 µg Inhalation Powder Device	USFDA	8	100
	MyTatva application COPD	DCGI	4	100
	Tiotropium bromide 18 µg dry powder inhaler	USFDA	24	324
	Tiotropium bromide 18 µg dry powder inhaler	USFDA	1	10
Misc	Cyclobenzaprine Hydrochloride Nasal Spray 0.35% w/v	NA	0	0
	Respiratory Mask	NA	1	25

REGULATORY EXPERIENCE - NORTH AMERICA

- We are abreast of all of the guidelines in Respiratory area.
- We have worked with our clients to shorten time-lines 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. Cliantha 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 Respiratory, Oncology, Dermatology, 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.

CLIANTHA ADVANTAGE

- Eminently qualified resource pool
- Greater understanding of regional complexities and culture
- Quick and focused decision making
- Better adaptability to constantly changing environment
- Trouble free access to numerous sites, investigators and patients
- Increased internal collaboration

Contact Cliantha today for more information about how we can enable you to make product launch decisions faster

For more information, write to us:
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