



## Expertise to Navigate the Complexities of Respiratory Research

Support your respiratory product development with our

- Therapeutic and regulatory experience
- Multi-geographic presence
- Innovative approach

## 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.

## 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

## LATE PHASE

	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
	Cyclobenzaprine Hydrochloride Nasal Spray 0.35% w/v	NA	1	10
	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	31	334
	Tiotropium 18ug Inhalation Powder, Hard Capsule, Inhaler Device	USFDA	1	10
Misc	Cyclobenzaprine Hydrochloride Nasal Spray 0.35% w/v	NA	1	10
	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's proprietary electronic tablet allows close monitoring of patients during long inhalation trials where they are on placebo.

## CLIANTHA ADVANTAGE



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

For more information contact:  
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