RESPIRATORY

EXPERIENCE - 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

RESPIRATORY EXPERIENCE: EARLY PHASE (INDIA)

STUDY NAME	#SUBJECT	STUDY TYPE DESIGN
Albuterol 4 mg Tablets - USFDA	30	Pivotal
	42	
	42	
	36	
	36	
	14	Pilot
	14	
Albuterol 90 µg ER- Tablets- USFDA - Fast	36	Pivotal
Albuterol Sulfate 90µg Inhalation Aerosol - USFDA	8	Pilot
	20	Pivotal
	14	Pilot
	60	Pivotal
Albuterol Sulfate 90 mcg per metered dose Inhalation Aerosol - USFDA	14	Pilot
	12	
Olopatadine Hydrochloride 665 mcg/spray Nasal Spray - USFDA	24	Pivotal
	12	Pilot

RESPIRATORY EXPERIENCE: LATE PHASE (INDIA)

MOLECULE	PHASE	INDICATION	SITES	PATIENTS
Glycopyrronium & Formoterol (Already launched in market)	III	Moderate or sever COPD	15	330
Beclomethasone Dispropionate	I & III	Persistent Asthma	15+20	480
Beclomethasone Dipropionate	505(b)(2) (DFS)	Mild Or Moderate Persistent Asthma	15+20	480
Fluticasone & Salmeterol (Advair)	III (CE)	Asthma	45+25	1204
Tiotropium	III (CE)	Asthma	25	273
Albuterol HFA Inhalational Aerosol	III	Asthma	10	20
Budesonide & Formoterol	III	Asthma	15	60
Albuterol HFA Inhalational Aerosol	III	Asthma	Based on pilot's result	116
Budesonide & Formoterol	III	Asthma	Based on pilot's result	600

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