

Expertise in Handling Inhalation Studies

www.raptimresearch.com



RAPTIM RESEARCH PVT. LTD.

A CONTRACT RESEARCH ORGANIZATION

THE CRO WITH REGULATORY COMPLIANCE EDGE

Raptim Research Limited's studies have been approved by FDA (US), TPD (Canada), EMA (Europe), WHO, MCC (South Africa), TGA (Australia), ISP Chile & ROW regulatory agencies.

Raptim is one of the most advanced CRO providing end to end clinical research services and In-vitro services to pharmaceutical, biotechnology and medical devices companies.

TYPES OF INHALED DRUG PRODUCT

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- +
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- +

INFRASTRUCTURE FOR INHALATION STUDIES

- State-of-the-art negative-pressure room for dosing activity for respiratory medications**
 - Provides uniformity in all major environmental factors for all respiratory dosing
 - To ensure there is no inter-subject unaccounted dosing via aerial contamination
 - Better regulatory acceptance due to well-controlled dosing procedure
- Inhalation Method training due to ensure compliance of well-controlled dosing procedure**
- Stringent criteria for volunteer selection for Inhalation study**
- Study subject training with placebo using special training device called Vitalograph prior to dosing**

WHY PARTNER WITH US?

- Understanding of Inhalation studies and its challenges, for clinical development phase**
- Start of the Art infrastructure for Inhalation studies**
 - Negative pressure area for dosing of Inhalation product
 - Excellent compliance volunteers database
 - Highly skilled & excellent scientific expertise
- Focused on volunteers training for smooth execution of Inhalation**
- Past experience of conducting various Inhalation studies (DPI, MDI, Aerosol)**
- Experienced team for frequent blood sample collection**
- Good understanding of regulatory requirements**
- Highly sensitive validated methods**

RAPTIM EXPERIENCE FOR INHALATION STUDIES

>> PK and PD Studies of Salmeterol + Fluticasone

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>> PK Studies of Budesonide DPI

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>> PK Studies of Salbutamol MDI

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>> PK Studies of Glycopyrrolate DPI

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UPCOMING PROJECTS: Beclomethasone MDI, Ipratropium Bromide MDI, Levalbuterol HFA

SERVICES OFFERED:

Bioequivalence Study, Analytical Services, BCS Bio-waiver Study, IVRT/IVPT, Kinetic/Binding Study, Clinical Study, Patient-PK Study, Data Management, Dermatology, Medical & Scientific Writing, Complex & Long Duration Study

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RAPTIM RESEARCH PVT. LTD.
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250+
BIOANALYTICAL METHODS

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