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veeda clinical research®

BIONEEDS

Inhalation Drugs Nearing Patent Expiry

Accelerating Development & Overcoming Challenges

Integrated Services Spanning the Full Spectrum of Drug Development Stages

Preclinical

- Acute/MTD Studies
- Dose Range Finding Studies
- Subacute Studies
- Sub Chronic Studies (90-days)
- Reproductive Studies (Teratology & Complete Response Rates (CRR))

Biopharma

- Clinical Bioanalysis solution for Bio Therapeutics
- Non-Clinical Characterization Solutions Discovery Biology, Bioprocess, and Analytical Characterization

Clinical Studies

- Phase I Clinical Pharmacology studies for NCEs & NBEs
- Phase II- Phase III trials for NCEs & NBEs
- Phase IV & PMS Studies
- Bioequivalence studies for Complex Indications like Chronic Obstructive Pulmonary Disease (COPD), Asthma & more

Bioanalytical

- Clinical Bioanalysis solution for Bion Therapeutics
- Non-Clinical Characterization Solutions Discovery Biology, Bioprocess, and Analytical Characterization

Complexities of Inhalation Drug Development: Key Challenges and Considerations

Formulation Complexity
Physicochemical properties and inactive ingredients affect drug performance and compatibility with devices

Safety Monitoring
Local and systemic side effects require careful monitoring and management

Dose Selection
Systemic concentrations are often extremely low, sometimes undetectable by standard bioanalytical methods

Volunteer Selection
Requires healthy, non-smoking volunteers for PK/BE studies or targeted disease patients for PD or clinical endpoint studies

Volunteer/Patient Training
Demands rigorous training for correct inhalation techniques, maintaining symptom diaries, and measuring exacerbations using EXACT-PRO for PD endpoints

Device Compatibility
Ensuring the drug formulation is compatible with inhalation devices for consistent dose delivery

Operationally Intensive
Volunteer management for cross contamination, PK sampling, Bioanalytical methods

Veeda's Proficiency in Inhalation Drug Delivery

- Successfully completed **42** inhalation studies
- Collaborated with global sponsors to submit studies to **USFDA, EMA, ANVISA, DCGI, and NMPA**
- Dedicated Recruitment team with a track record of enrolling **1700+** Volunteers
- Led by Senior Leadership Team with over a decade's experience and trained staff specifically for inhalation studies
- Focused training of each subject for accurate volunteer monitoring
- Equipped with negative pressure inhalation chambers
- **Partnered with an NABL** accredited laboratory for precise analysis

Inhalation Drugs for COPD: Patents Ending Soon

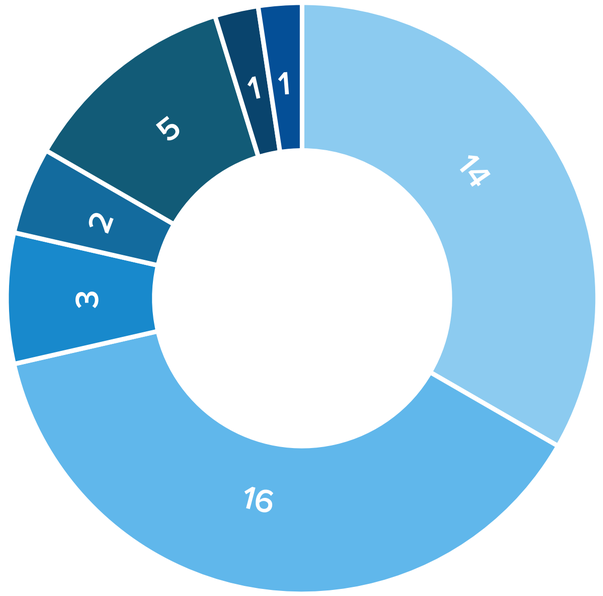
2025
Umeclidinium Bromide

2027
Fluticasone Furoate#umeclidinium Bromide#vilanterol

2027
Umeclidinium Bromide#vilanterol

2030
Formoterol#glycopyrronium

Experience with Various Complex Inhalation Drug Delivery Systems



- Pressurized Metered-Dose Inhalers (pMDIs)
- Dry Powder Inhalers (DPIs)
- Nasal Sprays
- Inhalation Aerosol
- Inhalation Powder
- Powder for Dispersion for infusion
- Inhalation Aerosol

Inhalation Infrastructure: State-of-the-art Negative Pressure Rooms

Advantages:

- Provides uniform environment with relatively consistent temperature, humidity, air flow, oxygen content and other major environmental factors for respiratory dosing
- Eliminates any chances of cross contamination from one dosed subject to another during dosing procedure
- Better regulatory acceptance due to assured well controlled dosing procedure

Optimizing Study Participation: Training Volunteers for Precise Inhalation Monitoring

Method

- Educating on actuation coordination
- Demonstrating proper inhalation technique
- Coaching on AIM device use
- Guiding with In-check DIAL meter
- Training with 2-tone device

Results

- Avoiding drug leakage
- Ensuring uniform inhalation rate
- Achieving precise inhalation flow interpretation

Inhalation Patient Trial Capabilities

Advanced Clinical Expertise and Robust Reach

- Experienced team members proficient in conducting two Phase III trials in moderate asthma, involving **650+** patients across **60+** active sites
- **25** sites in clinical endpoint studies
- **15** sites in patient PK studies

Network of Pulmonologist

- Database of **80** pulmonologists
- Centralized spirometry in COPD and moderate asthma patients
- **40** Hospital sites with registered IRBs

Building Trust through Extensive Regulatory Compliant Partnerships

- Temperature-controlled shipments for IMP and biological samples
- GMP-compliant repackaging services for IMP
- **15** sites in patient PK studies

Bioanalytical Method Development for Inhalation drugs

Sensitivity and Specificity

Ensured high sensitivity and specificity in LCMS methods for inhalation drugs, meeting the stringent requirements for bioanalysis in this therapeutic class. With sensitivity levels as low as 0.2 pg/mL for drugs like Formoterol and Tiotropium, we ensure precise and accurate quantification even at trace concentrations

Method Development using LC-MS

Developed robust LCMS-based bioanalytical methods for precise quantification of inhalation drugs like Fluticasone Propionate, Formeterol, Tiotropium, Budesonide, Salmeterol, Ipratropium, Formoterol (Sensitive), Becloamethasone Dipropionate + Beclomethasone 17-monopropionate, and Fluticasone Furoate + Vilanterol, covering a broad concentration range from Lower Limit of Quantitation (LLOQ) to Upper Limit of Quantitation (ULOQ)

Regulatory Compliance

Developed methods in accordance with regulatory guidelines (e.g., USFDA, EMA) for bioanalysis of inhalation drugs, ensuring data integrity and regulatory acceptance

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