We are a highly specialized, academia-affiliated research unit for early-phase and proof-of-concept clinical trials. Our focus is on airway diseases such as asthma, allergic rhinitis, COPD, and interstitial lung diseases, in particular idiopathic pulmonary fibrosis. We conduct trials with our highly qualified and dedicated team of physicians, study nurses, project managers, and medical documentation specialists, accompanied by an independent quality assurance unit. We offer a broad range of challenge models for our studies. With our strong academic background we support our clients in finding the proof-of-concept model and study design best suited to their particular requirements.

**Key topic**

Our excellent medical expertise and strong academic background give you assurance that we will find the optimal study design and proof-of-concept model for your clinical trial, especially in respiratory therapeutic areas.

**Our services and expertise**

- **Clinical Research Center Hannover (CRC Hannover)**
  - State-of-the-art facility
  - 6000 m² of floor space
  - 24/7 operations
  - 30 intensive-monitoring beds (for clinical trials of phases I and IIa)
  - 20 beds for study participants not requiring intensive monitoring
  - 15 rooms for special diagnostics

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From drug candidate to proof of concept

Development and manufacturing of biologics

Regulatory research and risk assessment

Preclinical testing

Clinical trials

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The Fraunhofer Institute for Toxicology and Experimental Medicine ITEM is one of about 70 institutions of the Fraunhofer-Gesellschaft, Europe’s leading organization for applied research. Protecting man from health hazards in our industrialized world and contributing to the development of novel therapeutic approaches are the aims Fraunhofer ITEM is pursuing with its contract research, with a focus on airway research.

In the area of drug development, we develop and test novel medications for treating respiratory diseases – in particular asthma, allergic rhinitis, chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, and infections. Our expertise ranges from the manufacturing of investigational biopharmaceuticals to preclinical and clinical development.

Your benefits

- Early-phase and proof-of-concept unit for airway diseases with unique infrastructure
- Broad range of challenge models
- Innovative diagnostics
- Academic expertise
- Customized testing strategies for early-phase trials
- Scientific synergies of in-house GMP production of investigational medicinal products, preclinical testing, and toxicology

- Imaging
  Non-invasive MRI techniques for quantitative assessment of pulmonary inflammation.
- GMP unit
  Handling of investigational medicinal products and production of final intravenous dosage forms in our in-house GMP unit.
- Patient/volunteer database and professional recruitment
  Large database of pre-screened patients and healthy volunteers and a professional recruitment unit guarantee rapid recruitment and reliable timelines in our clinical trials.

■ Fraunhofer Challenge Chambers
  Five challenge chambers for proof-of-concept studies, using natural pollen (grass, birch), allergen extracts (e.g. cat, house dust mite), hypoxia, or ozone.

■ Inhaled allergen challenge
  Induction of early and late-phase asthmatic reactions in patients with asthma, enabling efficacy testing of novel asthma treatments. A German multicenter network with the same high quality level across all participatory sites is available for expedited recruitment.

■ Segmental challenge by bronchoscopy
  Localized pulmonary inflammation (endotoxin, allergen) for the assessment of anti-inflammatory drugs or sampling of human material (under well-defined conditions).

■ Exercise testing (ergospirometry)
  Ergospirometry for efficacy testing of bronchodilators in patients with COPD.

■ Biobank
  Biological materials can be stored in our biobank at ultra-low temperatures.

■ Biomarker analysis
  Analysis of a wide range of biomarkers from blood, sputum, and lavage fluid in our state-of-the-art immunological laboratory (incl. flow cytometry, chip cytometry, MSD multiplex platform). Standardized induced sputum sampling and processing allows centralized analyses in multicenter trials that guarantee the highest level of quality.