



## DRUG DEVELOPMENT



## CLINICAL TRIALS

### Early phase and proof of concept

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.

#### Contact

Dr. med. Philipp Badorrek  
Phone +49 511 5350-8130  
philipp.badorrek@item.fraunhofer.de

Prof. Dr. med. Jens Hohlfeld  
Phone +49 511 5350-8102  
jens.hohlfeld@item.fraunhofer.de

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#### Key topic

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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.

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#### Our services and expertise

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- **Clinical Research Center Hannover (CRC Hannover)**
  - State-of-the-art facility
  - 6000 m<sup>2</sup> 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



*Biomarkers from blood, sputum, and lavage fluid are investigated with state-of-the-art methods.*

- Outpatient section for screening visits
  - Facilities for study participants, incl. cinema, gym, and cafeteria
  - Ability to house study participants for several weeks
  - Telemetric observation
  - Attendance of an anesthesiologist when required by protocol
  - Full set of emergency equipment and medication
  - **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.
  - **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.
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- Your benefits**
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- 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

### **Fraunhofer ITEM Clinical Airway Research**

Feodor-Lynen-Strasse 15  
30625 Hannover  
Germany  
Phone +49 511 5350-8102  
[www.item.fraunhofer.de/en](http://www.item.fraunhofer.de/en)

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.

#### **From drug candidate to proof of concept**

Development and manufacturing of biologics

Regulatory research and risk assessment

Preclinical testing

Clinical trials