



DRUG DEVELOPMENT



PRECLINICAL TESTING

Developing drug candidates to proof of concept

We offer preclinical studies with a focus on respiratory diseases such as asthma, COPD, infection, and pulmonary fibrosis. For this purpose, we use disease-relevant and toxicological test systems. Our studies are performed by a highly qualified and dedicated team of immunologists, biologists, toxicologists, and technical assistants. Based on our excellent scientific expertise, we assist our clients in the development of preclinical concepts.

Our experience with partners from the biotech and pharmaceutical industries forms the basis for scientific solutions and custom-tailored services. We assist our clients in developing preclinical testing strategies aimed at ensuring regulatory acceptance. Different cooperation schemes can be offered: from a joint publication to services aimed at advancing a drug product to the next development phase.

Key topic

We are committed to enabling reliable prediction of the efficacy and safety of drug candidates. To this end, we offer disease-relevant models for efficacy testing of drug candidates in all therapeutic areas of respiratory medicine and a broad range of toxicological tests enabling detection and assessment of potential risks to human health.

Contact

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The ex-vivo model of precision-cut lung slices from human lung tissue enables highly predictive non-clinical tests.

Our services and expertise

- **Efficacy testing of (bio)pharmaceuticals:**
 - Disease-relevant models for efficacy testing of drug candidates in all therapeutic areas of respiratory medicine: asthma, COPD, infection, fibrosis, and tumors
 - Broad range of cell, tissue culture, and animal models, used to study different disease aspects
- **Safety and toxicity testing of (bio)pharmaceuticals:**
 - In-vitro, ex-vivo, and in-vivo studies (relevant species, single-dose and repeated-dose toxicity)
 - Safety pharmacology (core battery)
 - Special focus on inhalation toxicology and immunotoxicology
 - Testing strategies to accompany clients during scientific advice and registration processes
 - Study performance in compliance with OECD GLP guidelines

Your benefits

- Preclinical tests with a focus on respiratory diseases, supported by a unique infrastructure
- Broad diversity of disease models for the respiratory tract
- Use of human tissue samples to improve predictivity of drug efficacy tests and for testing of biopharmaceuticals
- Quality guaranteed: the institute's GLP compliance has been continuously certified by the competent authorities since 1991
- Academic cooperation with the Hannover Medical School and the German Center for Lung Research (DZL), and involvement in numerous publicly funded research projects (German Research Foundation, German Federal Ministry of Education and Research, and European Union)
- Scientific synergies from in-house expertise, including GMP manufacturing of investigational medicinal products, pre-clinical testing, and toxicology

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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 pre-clinical and clinical development.

From drug candidate to proof of concept

Development and manufacturing of biologics

Regulatory research and risk assessment

Preclinical testing

Clinical trials