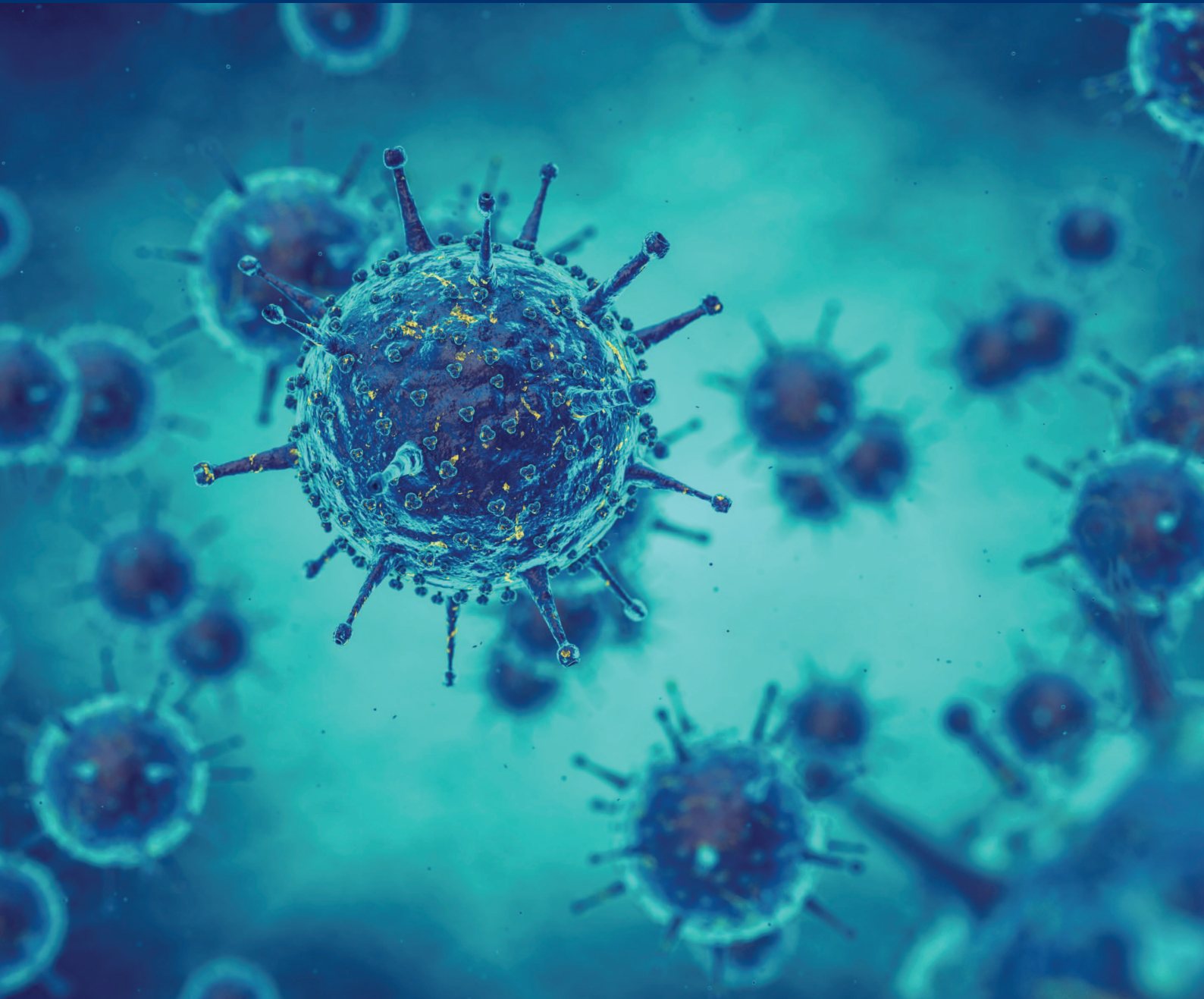
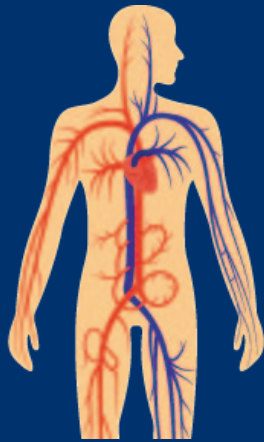


EARLY DIAGNOSIS AND INDIVIDUALIZED TREATMENT OF IMMUNE DISEASES





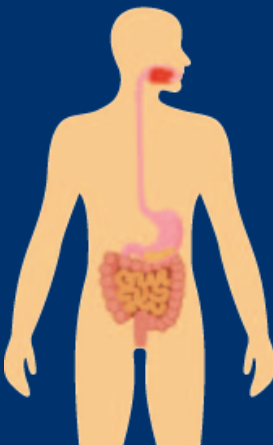
Inflammatory
rheumatic
diseases



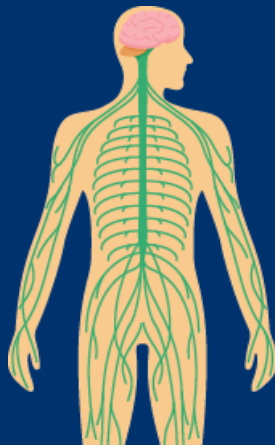
Vasculitides



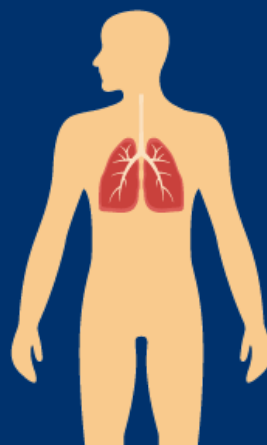
Inflammatory
dermatoses



Chronic-
inflammatory
bowel diseases



Immune-mediated
diseases of the
nervous system



Chronic
respiratory
diseases



IMMUNE-MEDIATED DISEASES: A THERAPEUTIC AREA WITH A GREAT NEED FOR RESEARCH

About eight percent of the population worldwide suffer from immune-mediated diseases. These conditions are very heterogeneous and can affect almost any organ or tissue. The therapeutic area of immune-mediated diseases includes, for example, rheumatoid arthritis, psoriatic arthritis, psoriasis vulgaris, the systemic disorder lupus erythematosus, atopic dermatitis and related allergy-induced conditions, but also chronic-inflammatory gastrointestinal diseases, chronic airway diseases, systemic sclerosis and multiple sclerosis. What many of these disorders have in common in terms of pathophysiology is a dysregulation of the immune system.

So far, immune diseases mostly have been treated symptomatically with drugs that non-specifically suppress the patient's immune system (immunosuppressive therapy). A treatment that fights the cause of the disease and, ideally, is individualized and cures the patient is not available at present. Both on pathophysiological issues and on potential therapeutic target structures there is a great need for research, which the Fraunhofer Cluster of Excellence for Immune-Mediated Diseases (Fraunhofer CIMD) wants to address.

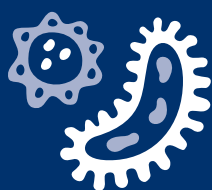




FRAUNHOFER CLUSTER OF EXCELLENCE »IMMUNE-MEDIATED DISEASES«

The primary goal of the Fraunhofer Cluster of Excellence for Immune-Mediated Diseases is the translation of innovative ideas and identified targets into individualized therapies for immune-mediated diseases. In the medium term, the collaborating institutes want to bridge the existing gap from research on novel medications to what is actually available to patients.

In forward-looking projects, three life science Fraunhofer Institutes – Fraunhofer Institute for Translational Medicine and Pharmacology ITMP, Fraunhofer Institute for Cell Therapy and Immunology IZI, and Fraunhofer Institute for Toxicology and Experimental Medicine ITEM – are pooling their expertise, thereby enabling efficient translation. In order to increase the value, networking with other Fraunhofer partner institutes outside the Life Science network, e.g. in the field of engineering and IT sciences, will be pursued. A substantial gain of knowledge in the pathophysiology of immune diseases will thus be generated, new diagnostic methods will be developed, innovative targets will be addressed, and new treatment categories in this therapeutic area will be introduced and established.



BIOMARKERS

LEAD DISCOVERY

TREATMENT CONCEPT

PRECLINICAL DEVELOPMENT

- Biobank
- Biopsies (synovia, pleura, liquid biopsy)
- Cell isolation
- Proteome, metabolome, and lipidome analyses
- Epigenetics
- Sequencing
- Next-generation cytometry
- Biosensors
- Single-cell diagnostics
- Omics platforms
- LC-MS/MS analyses

- Cryo-electron microscopy
- Multi-epitope ligand cartography
- Next-generation cytometry
- Mass spectrometry
- Cell-based assays
- High-throughput screening
- Drug design
- Medicinal chemistry

- Development planning and target product
- Profiles of innovative concepts and products
- Cost efficiency
- Genetically engineered cell therapy
- Therapeutic antibodies
- Nucleic acid-based therapy
- Chemically defined therapeutics
- Vaccination
- Omics technologies
- CyTOF technologies

- Cell-based human in-vitro systems (e.g. lab on a chip, 3D tissue models)
- Human organotypic systems (e.g. ex-vivo tissue cultures)
- Animal models (e.g. CRISPR / Cas9-based)
- Zebra fish models
- Insect models
- Imaging techniques
- Bioanalytics
- GLP testing (safety pharmacology, toxicology)



GMP MANUFACTURING

- Process development and GMP-compliant manufacturing (e.g. biopharmaceuticals, cell and gene therapeutics, candidate drugs, master and working cell banks)
- Formulation, sterile fill and finish
- Low-energy electron irradiation
- Quality assurance

CLINICAL TRIALS

- Clinical research center
- Acting as a sponsor
- Phase-I units
- Proof-of-concept studies, phase-I/phase-II trials, phase-IV trials
- Patient and volunteer database
- Clinical project management
- Clinical pharmacology
- Regulatory Affairs
- Pharmacovigilance
- Biostatistics
- Data management

REGISTRATION

- Regulatory expertise from the preclinical stage to market entry
- Health technology assessment and AMNOG processes

FROM MEDICAL NEED TO NOVEL MEDICATION

Development of a new drug must follow a multi-tiered process prescribed by legislation. It takes more than 13 years on average from the idea to the first market approval. The majority of this time is spent on studies to test the drug's efficacy and tolerability and to determine the most appropriate administration protocol.

PRECLINICAL PHASE



MEDICAL NEED

The focus is on the need to develop new medications for diseases for which no or only insufficient treatment is available so far.

CLINICAL PHASE



PHASE I: TRIAL IN SMALL NUMBER OF HEALTHY VOLUNTEERS

If preclinical testing was positive, the new investigational drug is tested in healthy adult volunteers. The focus of these tests is on the uptake and degradation of the new drug and the optimal dose.

REGISTRATION



EVALUATION BY THE AUTHORITIES

Experts once again evaluate the results of all trials. If the evaluation leads to a positive result, the drug can be approved and can henceforth be prescribed to patients.



TARGET DISCOVERY

Based on the results of basic research, researchers identify therapeutic targets and develop corresponding active substances.



SAFETY AND EFFICACY

The newly developed substances are first tested for safety and efficacy in cell cultures (in vitro) and animal models (in vivo).



PHASE II: TRIALS IN A SMALL NUMBER OF SUBJECTS WITH THE DISEASE

Based on the dose determined in the phase-I trial, the new drug is tested in volunteers with the disease or condition. The focus is on the new drug's efficacy (compared with placebo and existing drugs), tolerability, and dosage.



PHASE III: TRIALS IN A LARGE NUMBER OF SUBJECTS WITH THE DISEASE

Physicians in many different countries test the new drug in a large number of volunteers with the disease or condition. This allows less frequent side effects to be identified.



USE IN PATIENTS

Physicians, authorities, and the manufacturer monitor the drug's performance. The package insert, for example, is updated whenever needed.



PHASE IV STUDIES AFTER DRUG REGISTRATION

The drug is tested in further studies, for example to investigate interactions with other drugs or to find out whether it can be used in the treatment of other diseases as well.

HIGH-QUALITY BIOMATERIALS

High-quality biomaterials are essential for conclusive, unbiased medical research findings. In the context of immune-mediated diseases, collection of such materials is often a limiting factor. The biobanks of Fraunhofer ITMP, Fraunhofer IZI, and Fraunhofer ITEM store, for example, blood, tissue, stool, and urine samples. These biomaterials can be used for research purposes whenever required.

We have access to the following biomaterials from patients via our institutes' biobanks:

Diagnoses

- Ataxia teleangiectasia
- Asthma (LPS challenge)
- Asthma (rhinovirus challenge)
- COPD GOLD 1-4
- Eosinophilic fasciitis
- Lupus erythematosus
- Granulomatosis with polyangiitis
- Psoriatic arthritis
- Psoriasis vulgaris
- Rheumatoid arthritis
- Rhinitis
- Sarkoidosis
- Spondyloarthritiden
- Systemic sclerosis

Samples

- Bronchoalveolar lavage
- Citrate plasma
- DNA, RNA
- EDTA whole blood
- Skin biopsies
- Heparin plasma
- Lung biopsies
- Nasopharyngeal lavage
- PAXgene
- PBMCs
- Serum
- Stem cells
- Sputum
- Stool, urine
- Synovial fluid and synovia (tissue)
- Cells from BAL (bronchoalveolar lavage), NAL (nasal lavage), and sputum
- Cell culture supernatant



MEDICAL RESEARCH IN 4D

Fraunhofer CIMD is dedicated to translational research. It thus transfers basic research into the application. Fraunhofer is involved in the four major topics of health research - drugs, diagnostics, devices and data, the 4D. In principle, these represent four occupational groups: physicians, life scientists, engineers and computer scientists - who work under one roof at Fraunhofer. Thus, Fraunhofer has an excellent position to cost-effectively put ideas into practice and turn them into new treatment options.



DIAGNOSTICS

DATA

DRUGS

DEVICES



CONTACT

Central Office

Fraunhofer ITMP
Geschäftsstelle CIMD
Theodor-Stern-Kai 7
60590 Frankfurt am Main
GERMANY

Phone +49 69 6301 802 - 05 / - 57
info@cimd.fraunhofer.de

www.cimd.fraunhofer.de

Steering Committee

Prof. Dr. Dr. Gerd Geisslinger (Spokesman)
Institute Director at Fraunhofer ITMP

Prof. Dr. Dr. Ulrike Köhl
Institute Director at Fraunhofer IZI

Prof. Dr. Norbert Krug
Institute Director at Fraunhofer ITEM

Prof. Dr. Stefan Wrobel
Institute Director at Fraunhofer IAIS

Prof. Dr. Dieter W. Fellner
Institute Director at Fraunhofer IGD

PD Dr. Frank Behrens (Scientific Coordinator)
Deputy Director at Fraunhofer ITMP



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