

# How science can reach patients: Innovative structures for investigator-initiated research and development

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# Expertise and infrastructure of the Fraunhofer ITMP

## Agenda

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- **The Fraunhofer ITMP as part of Fraunhofer Health Research**
- **Research Area Clinical Research**
- **Clinical development**
- **Projects, platforms and networks**





# Fraunhofer Health Research

At a glance

## Transdisciplinary research for cost-intelligent solutions

- Health research comprises approx. 15% of the Fraunhofer R&D budget (3 billion/year)
- More than 40 of the 76 Fraunhofer Institutes conduct health research
- Translational, strongly interdisciplinary, market and product development-oriented focus

### The spectrum of Fraunhofer health research



Prevention



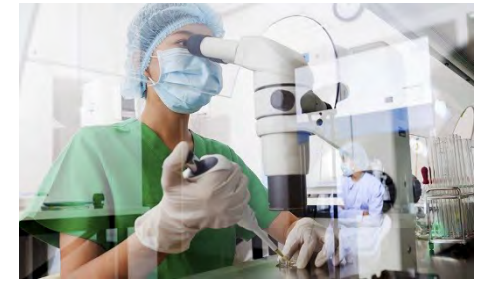
Diagnostics



Therapy



Care



**Mission** Translational health research for the benefit of the patient



**Vision** Cost-intelligent solutions for optimal healthcare delivery



**Strategy** Shaping medical progress with transdisciplinary cutting-edge research



# Health research is a cross-cutting issue at Fraunhofer

7 core institutes conduct health research exclusively



Fraunhofer Institute for Digital Medicine MEVIS



Fraunhofer Institute for Toxicology and Experimental Medicine ITEM



Fraunhofer Institute for Translational Medicine and Pharmacology ITMP

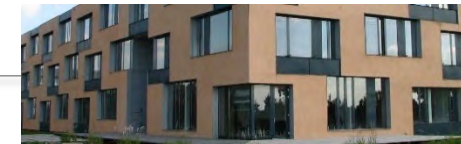


Fraunhofer Institute for Biomedical Engineering IBMT

Hauptstandorte ●  
Nebenstandorte ○



Fraunhofer Research Institution for Individualized and Cell-based Medical Technology IMTE



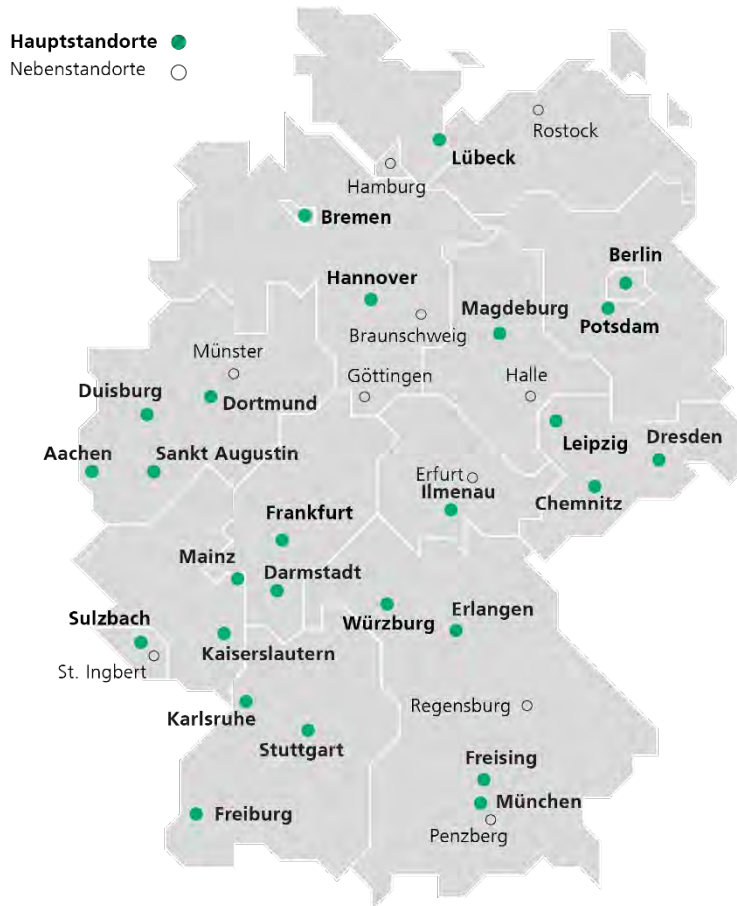
Fraunhofer Institute for Cell Therapy and Immunology, Department of Bioanalytics and Bioprocesses IZI-BB



Fraunhofer Institute for Cell Therapy and Immunology IZI

# Health research is a cross-cutting issue at Fraunhofer

More than 40 institutes are active in the field of health research



## Health network

7 core institutes with over 1,500 employees

### Focal points:

- Translational research
  - GxP
- Medical technology
- Medical Informatics
  - Clinical research
- Regenerative therapies

▶ 34 other institutes with technologies in the field of health research



# The Fraunhofer ITMP

## Structure of the ITMP

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- Independent **institute since 01.01.2021**
- Institute Director: **Prof. Dr. Dr. Gerd Geißlinger** (Executive Director)  
**Prof. Dr. Frank Behrens**

Subdivision into **three research areas** and **nine innovation areas**

- Currently **five locations**: Frankfurt (KGU) , Hamburg (UKE), Göttingen (UMG) , Berlin (Charité), Penzberg/Munich (LMU)





# The Fraunhofer ITMP with its main location in Frankfurt

Matrix structure across three research areas (cross-location...)

**Drug Screening & Compound Repurposing**  
A powerful platform for discovering compounds to investigate disease mechanisms and initiating drug...  
[GO TO INNOVATION AREA](#)

**Pharmaceutical Technology**  
Streamlining the formulation development of poorly soluble drugs by harnessing computational pharmaceuticals, rDCS, biorelevant in vitro testing and PBPK modeling.  
[GO TO INNOVATION AREA](#)

**Immunopathology & Immune Tolerance**  
Development of innovative pharmaceuticals capable of inducing...  
[GO TO INNOVATION AREA](#)

**Disease Models**  
Predictive preclinical and clinical disease models for the evaluation of disease hypotheses and characterization of active substances.  
[GO TO INNOVATION AREA](#)

**OMICS-Technologies**  
Generation of high-resolution molecular profiles to understand the...  
[GO TO INNOVATION AREA](#)

**Cross-functional Imaging**  
Innovative methods for the investigation of pathomechanisms up to the non-invasive visualization of disease patterns in patients.  
[GO TO INNOVATION AREA](#)

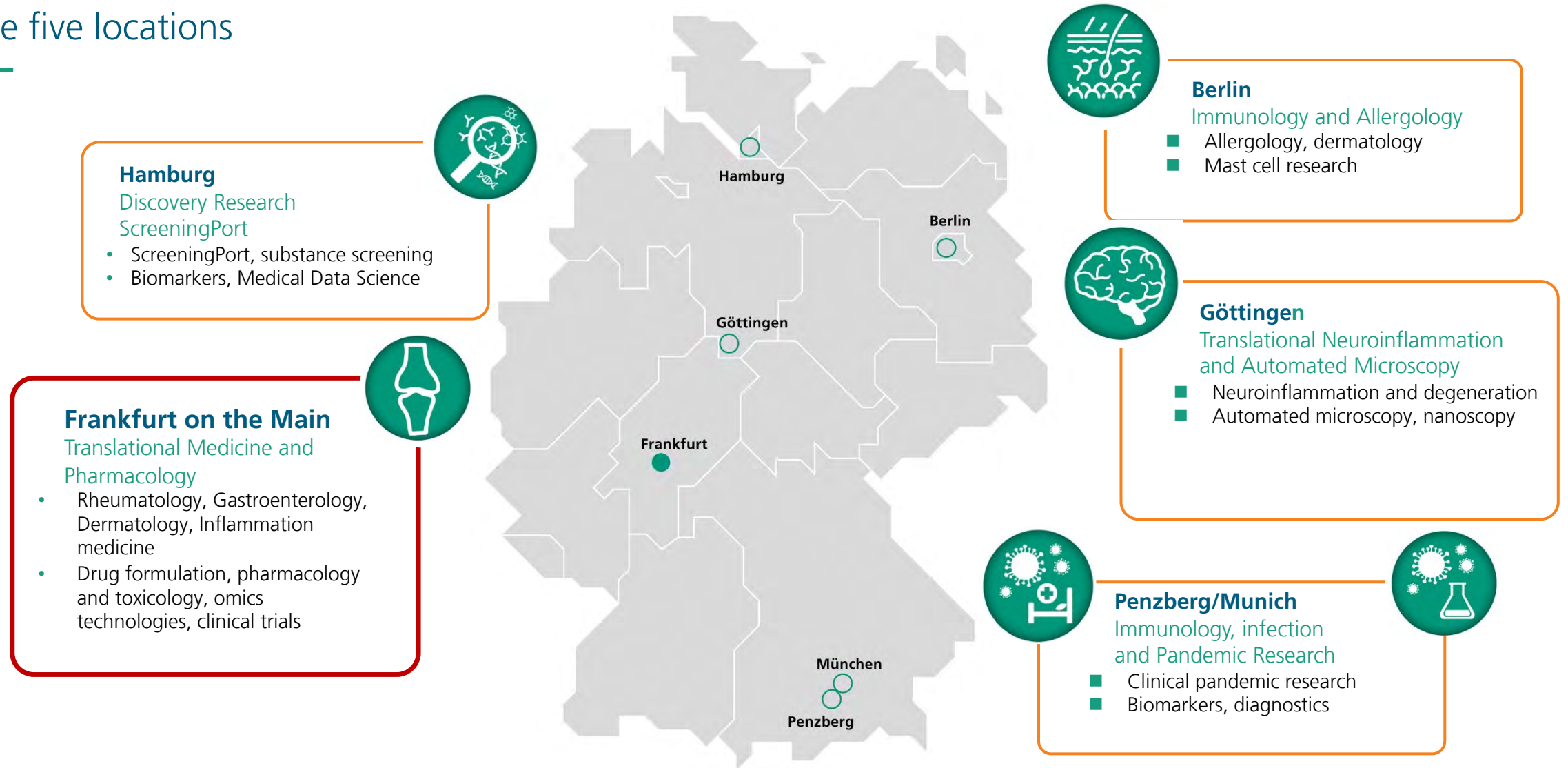
**4D Clinic**  
Optimized investigation and treatment of immune diseases by integrating transdisciplinary research along the 4D into interdisciplinary patient care.  
[GO TO INNOVATION AREA](#)

**Proof-of-Concept & Clinical Studies**  
Successful translation of preclinical innovations by optimized study design, quality-assured infrastructure and longtime experience.  
[GO TO INNOVATION AREA](#)

**Medical Data Science**  
Make FAIR enabled human data sets a key resource to enable health research.  
[GO TO INNOVATION AREA](#)

# The Fraunhofer ITMP

## The five locations





# Research areas Drug Discovery and Preclinical

## Overview



DRUG  
DISCOVERY



PRÄKLINISCHE  
FORSCHUNG

- Target identification
- Molecular design, medicinal chemistry
- Targeted protein degradation
- High Throughput Screening (HH)
- Formulation
- Antibodies and protein engineering
- Data Science (HH)
- Stem Cell Technologies (HH)



- In vitro pharmacology
- In vivo pharmacology
- Proteomics, Transcriptomics
- Models of immune-mediated diseases

Therapy-  
Concept

Target ID

Target  
Validation

Lead structure  
identification

Lead structure  
Optimisation

Preclinical  
validation



# Clinical Research ITMP - Frankfurt

Infrastructure for conducting clinical research projects/pharmaceutical studies



**GCP-compliant structure**  
based on **quality management system**



**Project management:**  
Study coordination, milestone monitoring, contract management, subcontractor management, regulatory affairs



**Conducting in-house studies (IIT)** and collaborations with biotech and small and medium-sized pharmaceutical companies



**Clinical monitoring:**  
Supervision and support of rule-compliant implementation at national and international study centres, coordinative and logistical support



**Project coordination:**  
administrative support in project initiation and during the course of the project



# Clinical Research ITMP - Frankfurt

Innovative study designs and evaluations



## Medical writing:

cooperation in the design of research projects/drug studies and study protocols.



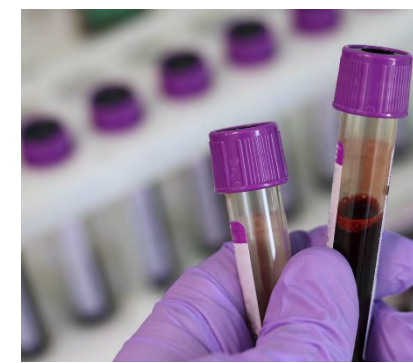
## Biostatistics:

Innovative caseload planning and data analysis; secondary analyses;



## Data management:

implementation of innovative scientific database and documentation systems according to applicable standards



## Study-related biomaterial collections:

Collection of samples from external centres for later evaluation and analysis in research projects with a focus on IMIDs



## Inflammation clinic:

Care-related and complementary infrastructure for trans- and interdisciplinary research of patients with IMIDs

# Clinical Research ITMP - Frankfurt

Analytics, phase 1 and research priorities



**Medical Bioanalytics:**  
Certified and accredited laboratory for the measurement of lipidomics and metabolomics



**Phase 1 Unit:**  
Conducting clinical trials in early drug development; pharmacokinetics

## Research focus



**Human Pain Models:**  
Objective measurement of pain in research projects and drug trials



**Characterisation of immunopathology:**  
research focus on spondylarthritides with a focus on psoriatic arthritis and early undifferentiated arthritis



# Project development

## Using the example of the MUST study



### Methotrexate plus ustekinumab versus ustekinumab monotherapy in patients with active psoriatic arthritis (MUST): a randomised, multicentre, placebo-controlled, phase 3b, non-inferiority trial

Michaela Koehm, Tanja Rossmanith, Ann C Foldenauer, Eva Herrmann, Jan Brandt-Jürgens, Gerd R Burmester, Herbert Kellner, Uta Kiltz, David M Kofler, Jürgen Rech, Sorwe Mojtahed-Poor, Christin Jonetzko, Harald Burkhardt, Frank Behrens, on behalf of the MUST Investigator Group\*

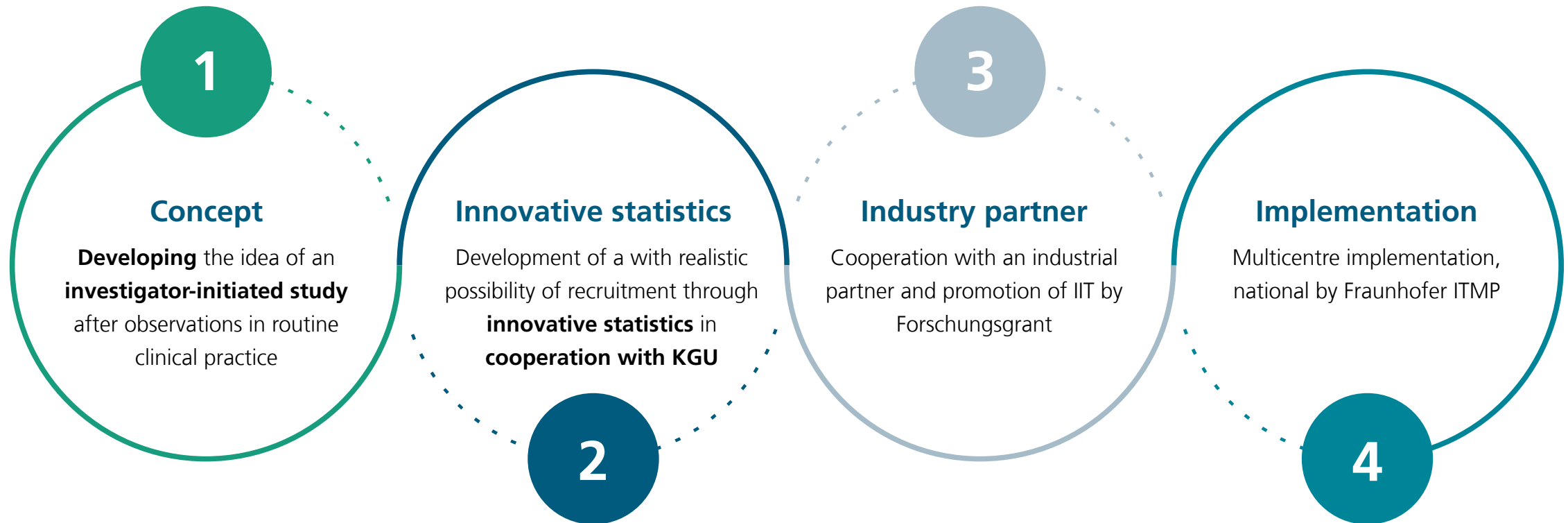
#### Summary

Lancet Rheumatol 2023;  
5: e14-23

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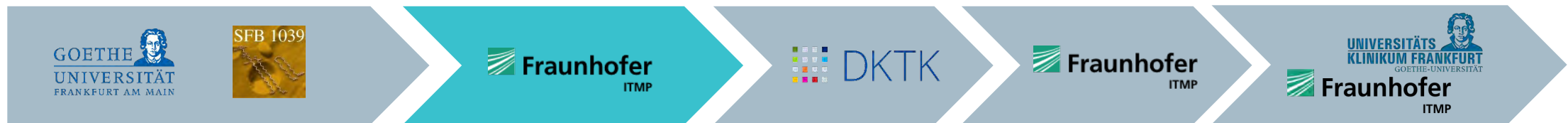
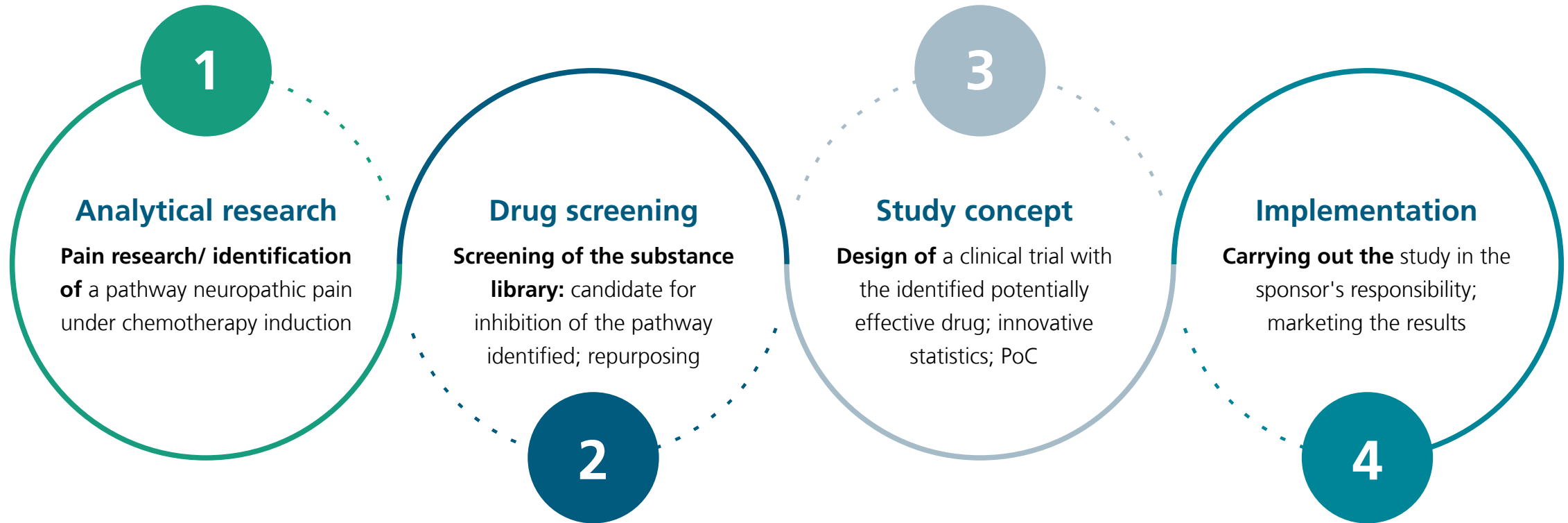
\*Collaborators are listed at the

**Background** The role of methotrexate in combination with biological agents in patients with psoriatic arthritis remains unclear. The MUST phase 3b trial aimed to compare the efficacy of ustekinumab plus placebo with ustekinumab plus methotrexate in patients with active psoriatic arthritis.



# Project development

## Using the example of the PrevTel project





# Early clinical development

## The example of FNAIT


- Preliminary work: Phase 0 study to establish an assay as part of an EU consortium.

### Final Report Summary - PROFNAIT (Development of a prophylactic treatment for the prevention of fetal/neonatal alloimmune thrombocytopenia (FNAIT))

#### Executive Summary:

PROFNAIT is a European Union-funded consortium ([www.profnait.eu](http://www.profnait.eu)) consisting of eleven Northern European hospitals, blood banks and companies, which aim to prevent 1,000 cases per year in EU and the US of potentially lethal or disabling internal bleeding in at-risk babies due to fetal and neonatal alloimmune thrombocytopenia (FNAIT). In spite of FNAIT being a rare condition, 13 leading EU and US medical societies in the fields of obstetrics and gynaecology have expressed their support of the PROFNAIT project and confirmed the unmet medical need in FNAIT.



**Deutsches Rotes Kreuz**   
**DRK-Blutspendedienst**  
Baden-Württemberg | Hessen  
gemeinnützige GmbH

 **Fraunhofer**  
IME



 **prophylix**

# Thank You!

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Fraunhofer ITMP & Fraunhofer Health  
as **competent partner in  
translation research and drug  
development**

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