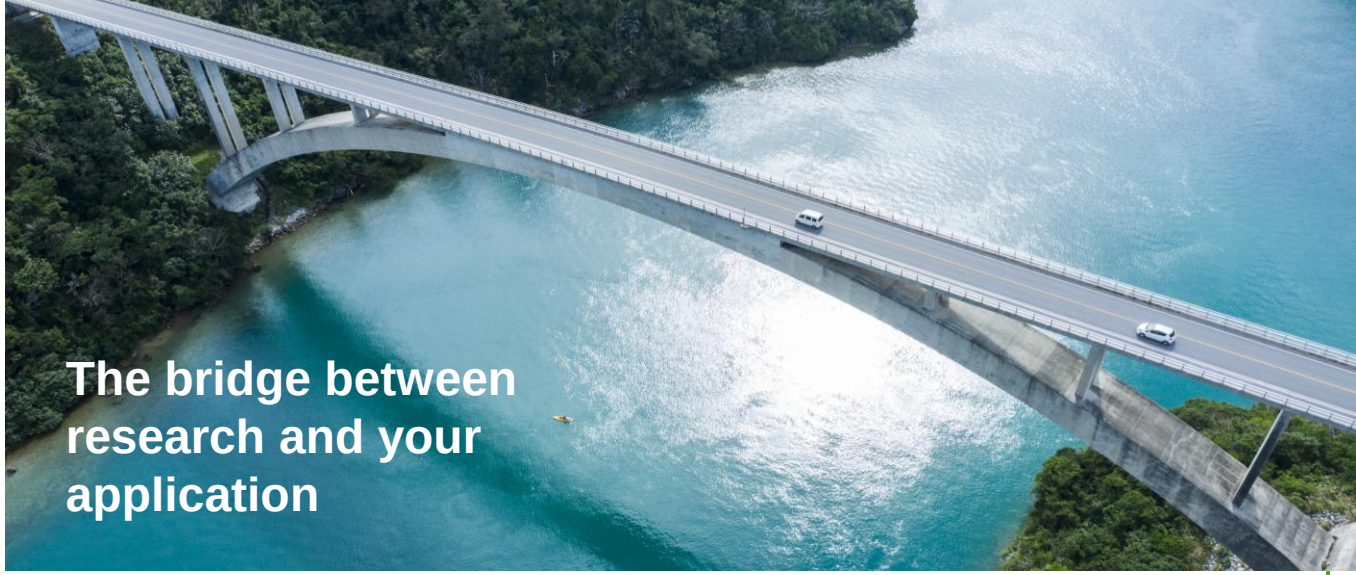

invite
- innovations
- visions
- technologies

Drug Delivery Innovation Center

DDiC
Drug Delivery innovation Center

Info Package, April 2025

2018 | 2019
INNOVATIVE THROUGH RESEARCH
Awarded by the Stifterverband
INV2413LEV

Drug Delivery Innovation Center

- The **Drug Delivery Innovation Center (DDIC)** which aims to bridge basic research and industrial applications officially started on **September 1st, 2017**.
- **Founding Tier 1 members** of the **open consortium** are the companies **Bayer AG, LB Bohle GmbH, Merck KGaA*** (all Germany) and **UCB S.A.** (Belgium), together with the university partners **TU Dortmund** and **HHU Düsseldorf**.
- The **consortium is complemented** by several **Tier 2 members** who support the work with material, equipment, software and know how.
- The **INVITE GmbH**, which is located in the CHEMPARK Leverkusen, Germany, **leads the consortium and builds the legal frame**.
- The consortium expands and we are looking forward to **discuss the opportunities of the DDIC with new members**.

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*known as Merck KGaA at Darmstadt, Germany, in the US and Canada

Vision and Mission
Drug Delivery Innovation Center (DDIC)

The DDIC is based on partnership and close collaboration between academia, industry and public stakeholders to become a world-class Center of Excellence in Drug Delivery Innovation. Based on established research platforms at the universities of Düsseldorf and Dortmund as well as at INVITE the DDIC will foster international, multi-disciplinary research networks.

- **Science**
  - Advance pharmaceutical science and innovation in close collaboration of multi-disciplinary networks with pharmaceutical industry (focus on pre-competitive research)
  - Increase fundamental process understanding as the base of advanced process control, modelling and prediction

- **Education**
  - The center supports the “master of industrial pharmacy” program at HHU Düsseldorf and offers a unique doctoral training program to develop a highly skilled talent base for industry and academia

- **Products & Innovation for Patients** (better healthcare for patients)
  - The center will accelerate patient-centric innovation, enabling the development of new technologies and advanced healthcare products and services

DDIC – a consortium of partners in academia and industry

A broad world-wide network of partners builds the basis for successful research as well as education and talent development to meet the needs of the pharmaceutical sector.

- **Multi-disciplinary research collaborations and consortia:**
  network of universities / research institutes from different disciplines
- **Pharmaceutical industry**:
  pre-competitive basis-oriented research and proprietary applications
- **Equipment Manufacturer**:
  new technologies for manufacturing and testing of pharmaceutical products
- **Pharmaceutical Suppliers**:
  excipient manufacturer, medical device industry (e.g., delivery technologies)

DDIC – innovative solutions for current challenges in the pharmaceutical industry

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Modeling and Prediction

- Rationale formulation design / pharmaceutical material science
- In-silico testing / prediction of biopharmaceutical properties
- Process modeling and simulation (DoE process optimization and scale-up)

Drug Delivery Technologies

- Oral, solid dosage form: Overcoming low solubility / poor bioavailability
- Inhalation technologies and ocular drug delivery (incl. medical devices)
- Advance formulations for biologics
- Drug Delivery for special patient groups (pediatrics & geriatrics)

Process Engineering

- Down-scaling (equipment & processes)
- Continuous Processing
- Advanced Process Understanding (incl. Design Space and Process-analytical technologies (PAT))

Future Technologies

- Nanomedicine, Nanotechnology
- 3D-printing
- Drug delivery for cell-based / gene therapy

DDIC Research Clusters

Seven research clusters have been defined by the Scientific Board

	Research Cluster
1	Low solubility / Poor bioavailability of oral drugs
2	Drug delivery forms for special patient groups / Personalized medicines
3	Continuous processing
4	Fundamental process understanding / PAT / Scalability
5	Models for predicting biopharmaceutical properties
6	Drug formulations for biomolecules (focus: mAbs and ADCs)
7	Nanomedicines / Nanotechnologies

DDIC Research Projects

Overview on 1st generation PhD theses, already finished (2017 – 2020/21)

	University	Group of	Title of PhD thesis
1	TU Dortmund	Prof. G. Sadowski	Thermodynamic and kinetic stability of amorphous solid dispersions (ASDs)
2	TU Dortmund	Prof. M. Thommes	Comparison of spray drying, hot melt extrusion and single pot technology in manufacturing of ASDs
3	TU Dortmund	Prof. G. Schembecker	Disturbance prediction in continuous manufacturing of oral solid dosage forms
4	TU Dortmund LMU Munich	Prof. G. Sadowski Dr. C. Brandenbusch Prof. G. Winter	Biopharmaceuticals: Stabilization and aggregation
5	HHU Düsseldorf U Greifswald	Prof. J. Breitkreutz Prof. W. Weitschies	Customized solid drug-loaded 3D-printed implants
6	HHU Düsseldorf	Prof. P. Kleinebudde	Evaluation of PAT tools for defining control strategies
7	HHU Düsseldorf	Prof. P. Kleinebudde	Regime maps for twin-screw granulation (TSG)
8	HHU Düsseldorf	Prof. J. Breitkreutz	Printed flexible drug-loaded instillations: Manufacturing and biopharmaceutical performance

DDIC Research Projects

Overview on 2nd generation PhD theses, currently running

	University	Group of	Title of PhD thesis
1	TU Dortmund	Prof. Gabriele Sadowski	Controlling Quality and Kinetics of Drying Processes for amorphous solid dispersions (ASDs)
2	TU Dortmund	Prof. Markus Thommes	Comparison of numerical approaches in modeling of pharmaceutical hot melt extrusion processes for ASD production
3	HHU Düsseldorf	Prof. Joerg Breitkreutz	Fate of amorphous particles in the GI-tract
4	HHU Düsseldorf	Prof. Joerg Breitkreutz	In vitro and in silico physiology based pharmacokinetic (PBPK) modeling of pediatric drug formulations
5	HHU Düsseldorf	Prof. Joerg Breitkreutz	Small matrices (Minitablets) with extended drug release properties
6	HHU Düsseldorf	Prof. Michael Hacker	Amino acid-derivatized amphiphiles for stabilization and release of highly concentrated and low viscous formulations of protein/antibody
7	HHU Düsseldorf	Prof. Anne Seidlitz	Gel printing of clinical batches for early clinical phases
8	LMU Munich	Prof. Olivia Merkel Prof. Wolfgang Friess	Development of stable RNA nanoparticle powder formulations for inhaled delivery

Current Academic Partners

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Heinrich Heine Universität Düsseldorf	Prof. Dr. J. Breitkreutz Prof. Dr. Dr. h.c. P. Kleinebudde Prof. Dr. M. Hacker Prof. Dr. A. Seidlitz
technische universität dortmund	Prof. Dr. G. Schembecker Prof. Dr. G. Sadowski Prof. Dr. M. Thommes Dr. C. Brandenbusch
UNIVERSITÄT GREIFSWALD Wissen lockt. Seit 1456	Prof. Dr. W. Weitschies
LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN	Prof. Dr. G. Winter Prof. Dr. O. Merkel Prof. Dr. W. Friess
GHENT UNIVERSITY	Prof. Thomas de Beer

DDIC Current Members

Current status of DDIC members

- **Tier 1**
  - Bayer AG
  - Merck KGaA
  - Johnson&Johnson Innovative Medicine (Janssen N.V.)
- **Tier 2**
  - Ashland Industries Deutschland GmbH (Excipients)
  - Bohle Maschinen & Verfahren GmbH (Manufacturing Equipment)
  - DFE Pharma (Excipients)
  - DigiM (Digital Images, SME)
  - INOSIM Software & Consulting GmbH (Production Process Simulation, SME)
  - Nisso Chemical Europe GmbH (Excipients)
  - Parsum GmbH (Inline Probes Particle Size Measurement, SME)
  - Phoenix Contact (Electronics and Automation)
  - Physiolution GmbH (GI-tract Simulated Dissolution, SME)
  - Siemens AG (Digital Twins, PSE Enterprise)
  - Solid-Chem (Solid State Characterization, SME)
  - Syntegon (Manufacturing Equipment)
- Managing the Tier 2 community: Sean Bermingham (PS Enterprise / Siemens) as representative in SB-meeting

The DDIC provides a range of benefits to its members

- Access to the Open-Innovation Platform at INVITE with a unique network of partners along the pharmaceutical value chain
- Unique opportunity to work on pharmaceutical and process engineering issues simultaneously and jointly with recognized university chairs
- Shape technology development in the area of drug delivery with partners in academia and industry in a pre-competitive environment
- INVITE offers the capabilities and experience (e.g. F3-factory) to set-up and successfully run publicly funded projects. Partners of DDIC will have the opportunity to join the (international) consortia for these projects
- First-hand insights into all joint research projects (20-30 PhD and master programs in steady state envisioned together with partner universities), thus substantially increasing return on own research investment
- Option to run proprietary research projects as part of on-going PhD-studies or as separate PhD-studies with option to use Invite facilities
- Temporary staff exchange (to DDIC or from DDIC to company) for training and development of new capabilities.
- Access to talents (i.e. graduates of PhD and master programs)
- Technical non-exclusive, world-wide license to IP developed at the DDIC

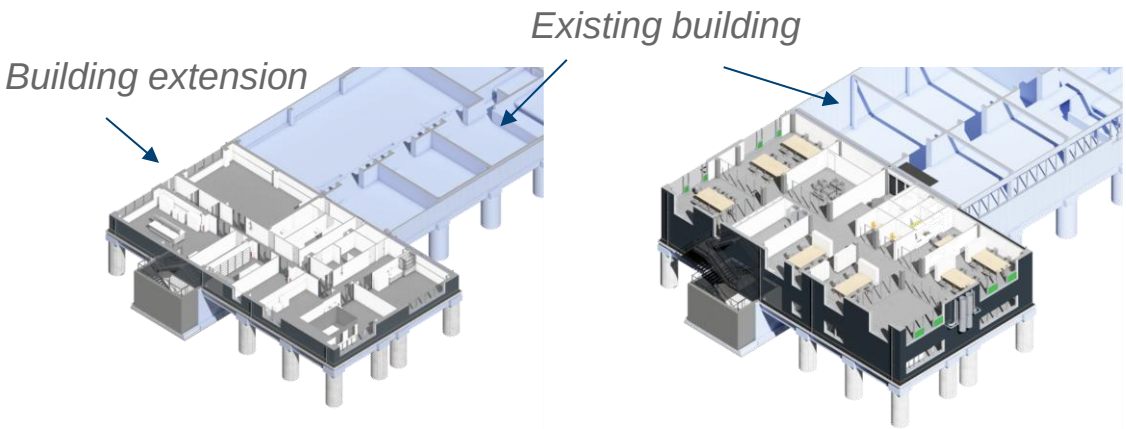
Lab facilities open for use by members

Currently available facilities

- 3 labs with ~70 m^2 for handling active ingredients of OEL 3

New lab and pilot plant facilities commissioned in Feb 2024

- Additional lab area of ~600 m^2 for handling active ingredients up to OEL 4



DDIC Membership Concept

Two options to become a member within the DDIC consortium

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Trial membership possible

Tier 1

200 k€ p.a. for 3 years

- Member of Scientific Board (SB)
  - *Definition of research topics at DDIC*
- Full access to Technical Committees (TC)
  - *PhD program review*
  - *Steering the content of running theses*
- PhD mentoring
  - *Individual PhD project possible*
  - *Test technologies with your own materials*
- Free technical licenses to all IP
- Opportunity to use Invite facilities

- Further:
  All rights granted to Tier 2 partners

Tier 2

in-kind or cash contribution for 3 years

- SB: One representative of all Tier 2 partners
- For projects with material contributions
  - *PhD program review in TCs*
  - *Test your product in a highly visible environment*
    → *Results are later part of publications*
  - *Royalty-bearing licenses*
- Access to
  - *DDIC report data base, publications*
  - *DDIC facilities*
  - *Talent pool*
    → *observe your future employee over a long period of time*
  - *Public funding consortia,* Scientific network
  - *Technology trends*
- Preferred partner for community

Executive Summary

- The Drug Delivery Innovation Center (DDIC) builds on strong academic research and many companies in the pharmaceutical sector and will expand to create an international, multi-disciplinary network in the area of Drug Delivery Innovation.
- The center aims to bridge basic research and industrial applications, strengthen pharmaceutical education (master of industrial pharmacy and PhD-programs) and ultimately deliver patient-centric innovation for better healthcare.
- The location – directly connected to INVITE and the CHEMPARK Leverkusen - provides the optimal infrastructure for research and can be easily reached by private and public transportation.

- The DDIC offers a privileged membership to a broad range of players in the pharmaceutical industry along the value chain.

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