3D PHARM CHANGE

DEDICATED DRUG DEVELOPMENT XPERTS

A Complete Solution to (Bio-)Pharmaceutical Development

May 2025

About Us

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

Founded in 2010 by a team of experts with individual experience of **+20 years**

40+ experienced experts at MSc and PhD level

Client-focused consultancy services

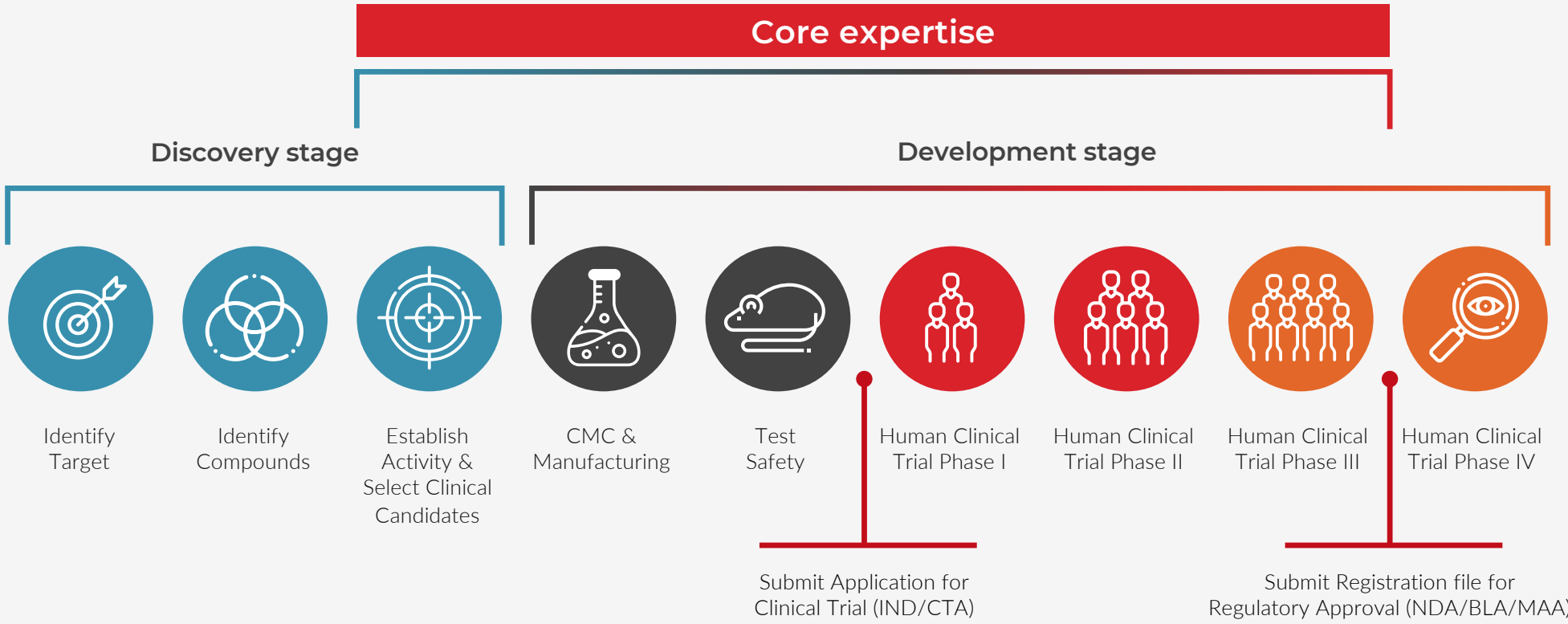
Client satisfaction rates **> 90%**
85% returning customers

Vast **international** experience

Extensive **experience** with EMA, FDA and National EU Health Authorities

3D-PharmXchange:
Your Drug Development Partner

3D PHARM X CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS



3D-PharmXchange

3D PHARM X CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

- Integrated multidisciplinary approach
  - CMC & Quality Assurance
  - Non-Clinical
  - Clinical
  - Regulatory Affairs
- Wide range of expertise
  - Experience with a wide range of clinical indications & routes of administration
  - Small Molecules, Biologicals, LNPs, Cell & Gene Therapy
  - MAA/NDA
- Highly experienced
  - Senior expertise (incl. C-level)
  - Consultants with broad industrial experience
  - Experience with Small and Large Pharma & Biotechs
- Dedicated Project Management & Leadership

Our core expertises

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CMC

- ✓ CMC strategy
- ✓ C(D)MO selection & management
- ✓ Development of small molecules, biologics & cell & gene therapies
- ✓ Clinical supplies
- ✓ CMC regulatory documentation

Including

- QA/QP support
- CMC RA support

Non-clinical

- ✓ Toxicology
- ✓ ADME
- ✓ (Safety) Pharmacology
- ✓ Toxicokinetics & Bioanalysis
- ✓ Good Laboratory Practice
- ✓ Biomarker development

Including

- Strategy & execution
- CRO selection & monitoring
- Study design
- FiH dose selection and rationale
- Combination therapies

Clinical

- ✓ Clinical development Strategy
- ✓ Innovative Study design
- ✓ Protocol Development
- ✓ Pharmacokinetics and PKPD Modeling
- ✓ Clinical Operations
- ✓ Good Clinical Practices

Including

- Development strategy
- CRO selection & monitoring
- Clinical documents
- Statistical expertise
- Adaptive clinical study designs, Platform Clinical Trials etc.

Regulatory

- ✓ Regulatory Strategy
- ✓ Scientific Advice / Protocol Assistance
- ✓ Reports and Submission
- ✓ Health Authority Interactions incl. EMA, FDA
- ✓ Pediatric Investigational Plans

Including

- Advanced therapies
- Orphan drug designation
- SME status
- Life Cycle Management
- Repurposed Medicines

Project Management & Leadership

Why you should partner with us

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

Small Teams	Experienced	Specialized expertise	Agile
Dedicated & focused	All consultants have industrial experience	Multiple indications & administration routes	Engaged with start-ups as well as large biotech & pharma
Short communication lines between disciplines	Familiarity with processes & regulatory aspects	e.g. SMEs, ATMPs, viral delivery, polymeric delivery	Tailored, fit for purpose projects with appropriate risk mitigation
Time effective through rapid multidisciplinary decision making	Cost effective drug development	Access to smart clinical design & expert (non-) clinical science	Flexible, adaptable and customer-centric

Key Achievements

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Large Biotech
Triple combination therapy
Project management & Tox

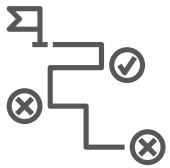
- ✓ Project leadership of 60FTE
- ✓ Clinical PoC

Small Pharma
Intranasal Delivery & Smart Clinical Design

- ✓ Novel Drug – Device combination
- ✓ Full Development support
- ✓ Smart Clinical Design – Single phase 1 PKPD study
- ✓ Positive feedback CBG (MEB) and EMA Scientific Advice
- ✓ Successful registration & commercialization

Investor
Due diligence

- ✓ Operational and commercial due diligence



Mid Biotech
Gene therapy
CMC support

- ✓ CMC Project leadership of 2 lead programs
- ✓ Tech transfer from EU to US

Mid Pharma
Small molecule: integrated development

- ✓ Non-clinical development of 3 parallel programs


ANTIBODY-DRUG
CONJUGATES
PEPTIDES
METABOLIC
DISORDERS
INFECTIOUS DISEASES
RESPIRATORY
CHRONIC PAIN
NEUROLOGICAL
DISORDERS
SMALL
MOLECULES
DERMATOLOGICAL DISORDERS
KIDNEY INJURY
GENE THERAPY
OPTHALMOLOGY
CELL THERAPY
CARDIOVASCULAR
(IMMUNO-)ONCOLOGY
VACCINES
BIOLOGICS
ATMPs
POLYMERS
BISPECIFICS
ANTISENSE
OLIGONUCLEOTIDES
LNPs

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