Pioneering Perspectives: Innovation and Technology in Early-Stage Clinical Drug Research

Geert Jan Groeneveld, Centre for Human Drug Research (CHDR)



Harnessing technology for human drug research

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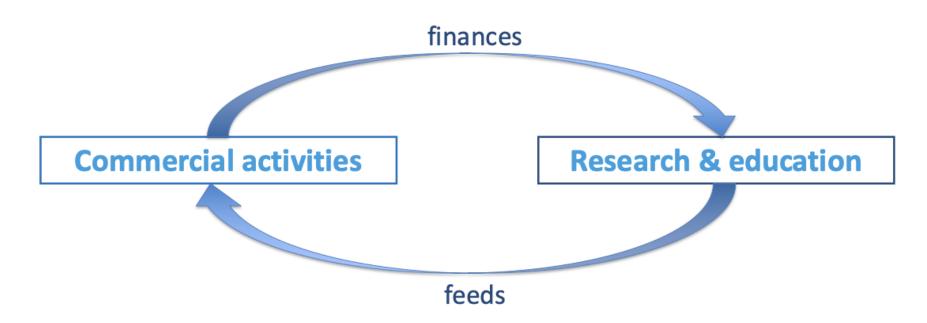
Executive summary CHDR

- > Contract research organisation, established in 1987 as a foundation
- > 280+ full time equivalent employees
- > Profit used for innovation
- > Development and validation of clinical pharmacology methods & biomarkers
- > Training site (PhD, undergraduate students, clinical pharmacology education)
- > Approximately 55 early phase clinical trial projects per year for big pharma & biotech
- > Studies in healthy volunteers and patients
- > Proof-of-pharmacology
- > Proof-of-mechanism
- > Ready-for-Research
- > CHDR Monocentre
- > Housed in a purpose-built, world class facility (opened in 2013), 54 beds
- > In-hospital CRU with 8 beds in the Leiden University Medical Center (LUMC)
- > Close collaborations with top Universities & Medical Centres





CHDR's unique model





2023 at a glance





>20,000



43









81







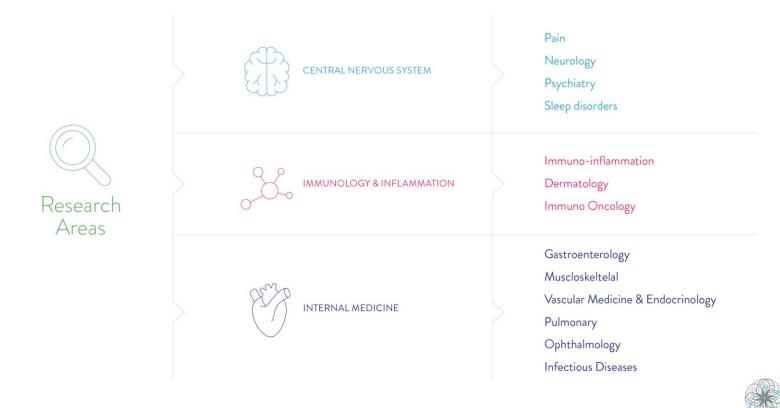
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Research areas

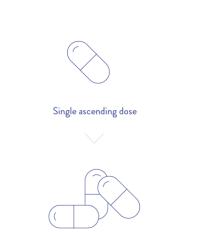


Early-phase drug development









Multiple ascending dose







Surrogate endpoints in patients
Efficacy in patients

POP: Proof-of-Pharmacology

POM: Proof-of-Mechanism

Innovative tools for 'Proof-of-Pharmacology'

- > NeuroCart®
- > PainCart®
- > Neuroimaging
- > Inflammatory challenges
- > CSF-Sampling
- > CNS pharmacological challenge models
- > Driving simulator
- > Metabolic challenges
- > Hormone clamps
- > Cardiac & Endovascular function assessments
- > Coagulation tests
- > Dermatological assessments Derma Toolbox®
- > Retinal imaging
- > In-vitro & ex-vivo immunological challenges



Collaborative model

Examples collaboration networks: patients, methods & key opinion leaders

- > Parkinson's Disease network
- > LUMC, Amsterdam UMC, Haga ZH, others
- > ALS collaboration
- > UMC-Utrecht
- > Dermatology (CONNECTED)
- > LUMC, Erasmus MC, 10+ dermatological clinics
- > Pulmonary Collaboration
- > Erasmus MC
- Vascular medicine & Inflammation Collaboration
- > LUMC, Amsterdam UMC

- > Immuno-oncology
- > LUMC, Haga ZH, NKI
- > Neuroregeneration Network
- > LUMC, Erasmus MC
- > Cardiology Network
- > Amsterdam UMC
- > Ophthalmology Network
- > Eye hospital Rotterdam
- > ...and many others.



New clinical research unit: CHDR-Twente @ MST

- > 12 research beds
- > 3 research rooms
- > 2 screening rooms
- > living area for study subjects
- > office space for employees
- > cantine





Mission alignment

>UT

> "To impact society through the <u>development</u>, evaluation, and appropriate implementation <u>of technology</u> leading to sustainable and personalised health for everyone"

>CHDR

"Adding value to early-phase clinical drug development to realise better drugs for patients"

>MST

> "Promoting health in the Twente region in close collaboration with regional care partners, training new healthcare professionals and conducting scientific research"

→ "Technology assisted drug development"



