

Academic Pharma

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Disclosures

Name:

Teun van Gelder, MD, Leiden Univ Medical Center, Netherlands

Commercial Interests & Nature of Relationships:

- Roche, Astellas, Aurinia, CSL Behring, Chiesi, Roche Diagnostics, Thermo Fisher: Consultant/Speaker received honoraria
- Chiesi and Astellas: Research Grant Support, study on transplant related diseases
- I am an employee of LUMC



Discovery and development:

Basic science:

- New targets
- New compounds

Translational research

Clinical studies:

- Phase 1
- Phase 2
- Phase 3

Registration









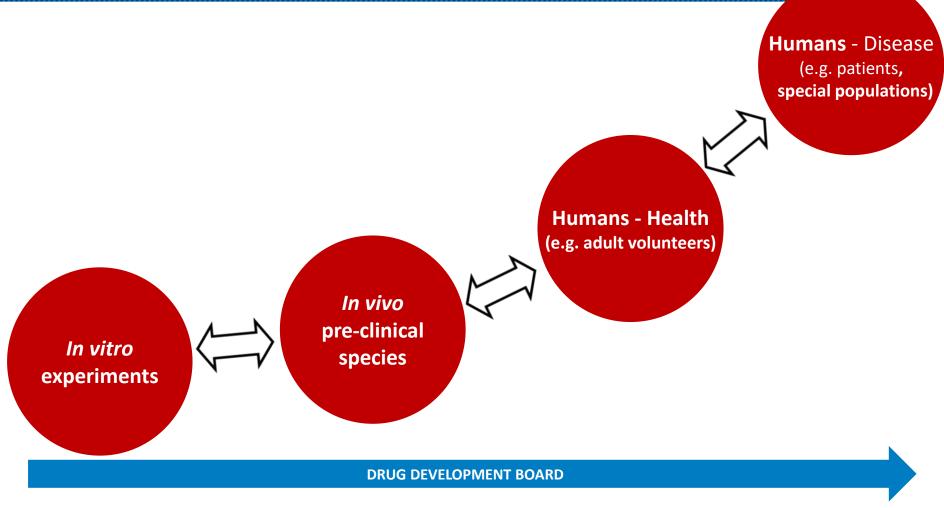
The Leiden Landscape



Landscape for drug development:

Leiden Institute for Chemistry, LACDR, CHDR, LUMC, Leiden BioScience Park, TNO

Team work



Target finding
Drug lead synthesis
Proof of pharmacology

Preclinical toxicity Metabolism & PK Effectiveness GMP manufacturing First in man Phase I Safety, PK Proof of effectivity Safety, biomarkers Comp. efficacy

Leiden

University Leiden Research Program 'Translational Drug Discovery & Development'

Matched funding from strategic fund LUMC:

Academic Pharma 2.0: Innovative drugs from bench to bed-side.

LUMC STRATEGIE 2018-2023



Perspective of "the" academic researcher:

- Focus on science, innovation, top-publications.
- Focus on own domain, not on development plan or pipeline.
- After finishing project: risk that finding ends up on a shelf.
- Missed opportunities.
- Academic freedom.
- Less awareness for intellectual property or valorisation.
- Perception that fundamental research is a higher goal than bringing compound to patient

Aiming high

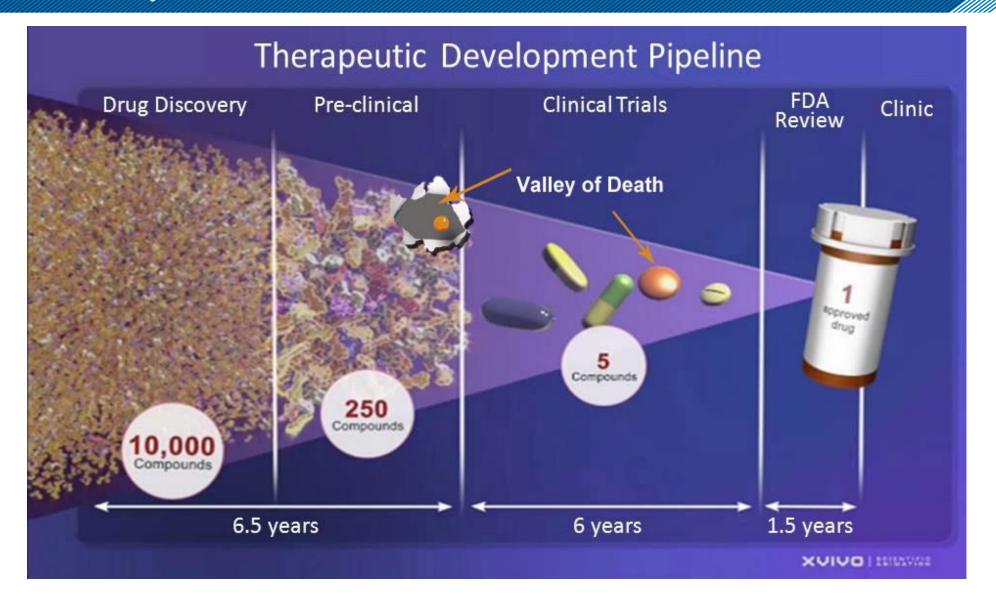
Registration of drugs:

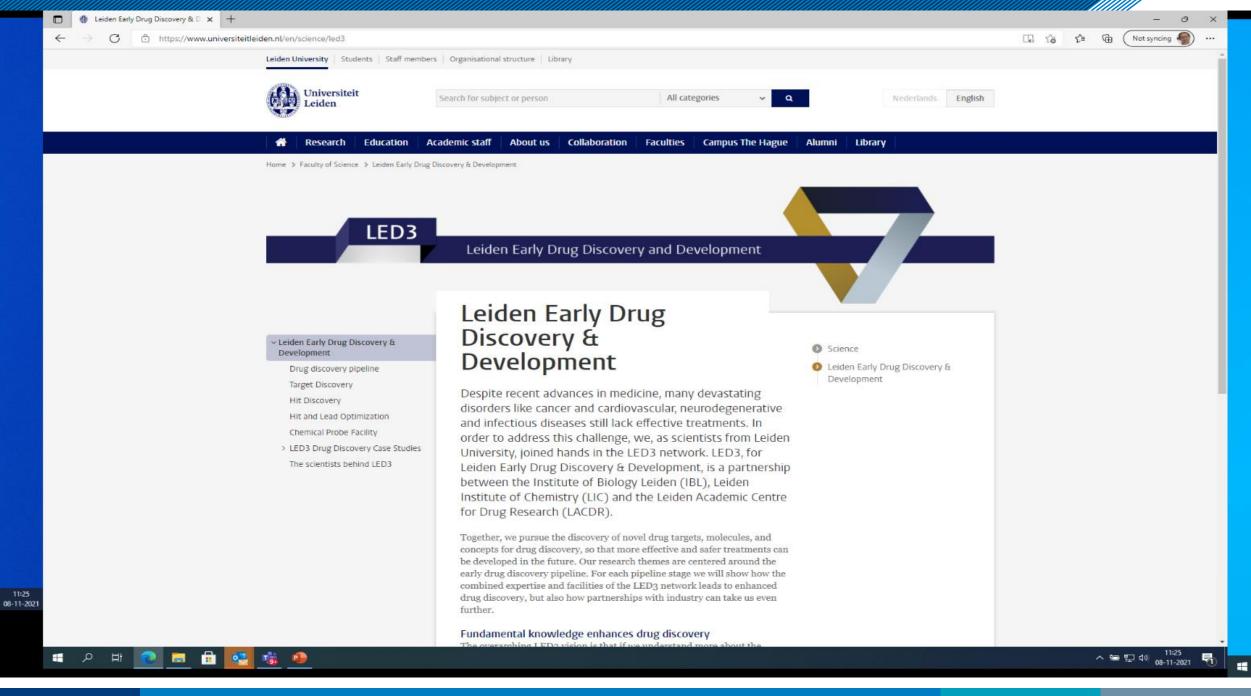
Complex.

For academia the same rules apply.



The valley of death





Support from Academic Pharma:

- Awareness of (im)possibility of protecting intellectual property
- Publication Y/N
- Non Disclosure Agreements
- Project based approach: start with the end goal.
- Awareness of impact of regulatory issues
- Possibility scientific advice
- Funding

Academic Pharma:

- No "me too" drugs
- No generic production
- Unmet clinical need
- Rare diseases, compounds without patent are welcome
- New Chemical Entities, as well as repurposing
- Protect magisterial preparations against price hikes

Academic Pharma

Not our ambition to be a big drug factory

Licencing agreements

National Farmaceutic Knowledge Center (NFKC)

Stichting Nationaal Farmaceutisch Kennis-, Ontwikkel- en Opleidingscentrum. (opgericht door LUMC, TNO, LBSP op 29 juni 2020)

Goals:

- Support the development of innovative drugs in academia
- Develop and offer expertise in drug development to academic researchers
- Teach and train students, PharmDs, MDs, MScs... in drug discovery and development

FAST





National expertise center



Conclusions & Discussions

- Academic Pharma has been put on the map.
- Complementary to (big) pharma.
- Crossing the valley of death.
- Develop expertise, bundle forces, support academia.
- Local versus national.