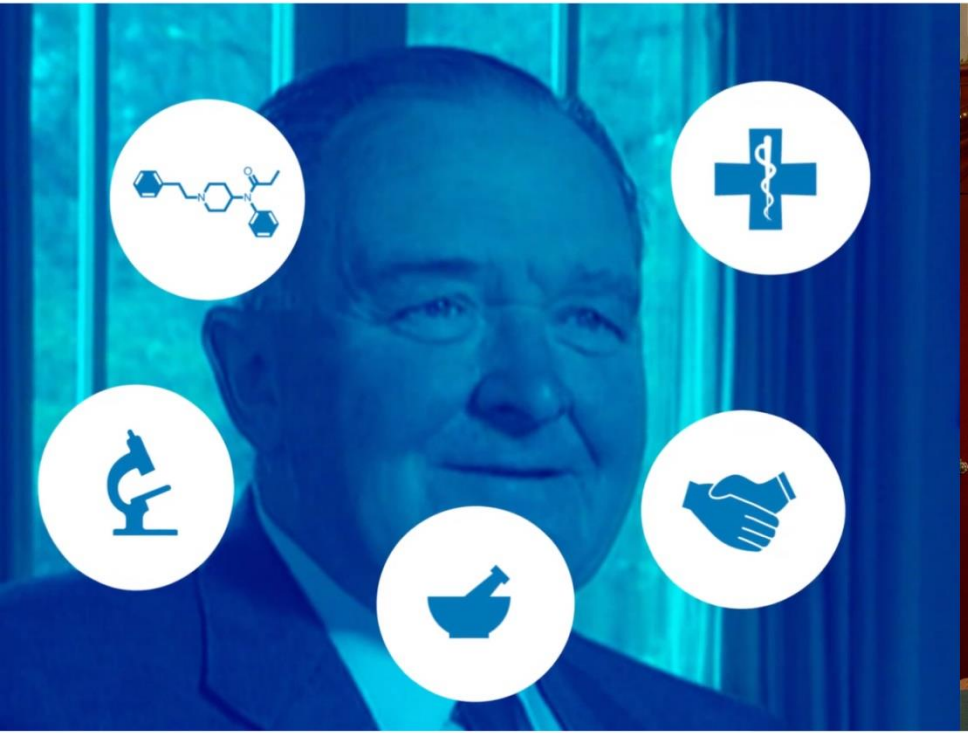
Our contributors

Paul Janssen Futurelab Leiden

Marcel Kenter
Director

Leiden University Medical Center

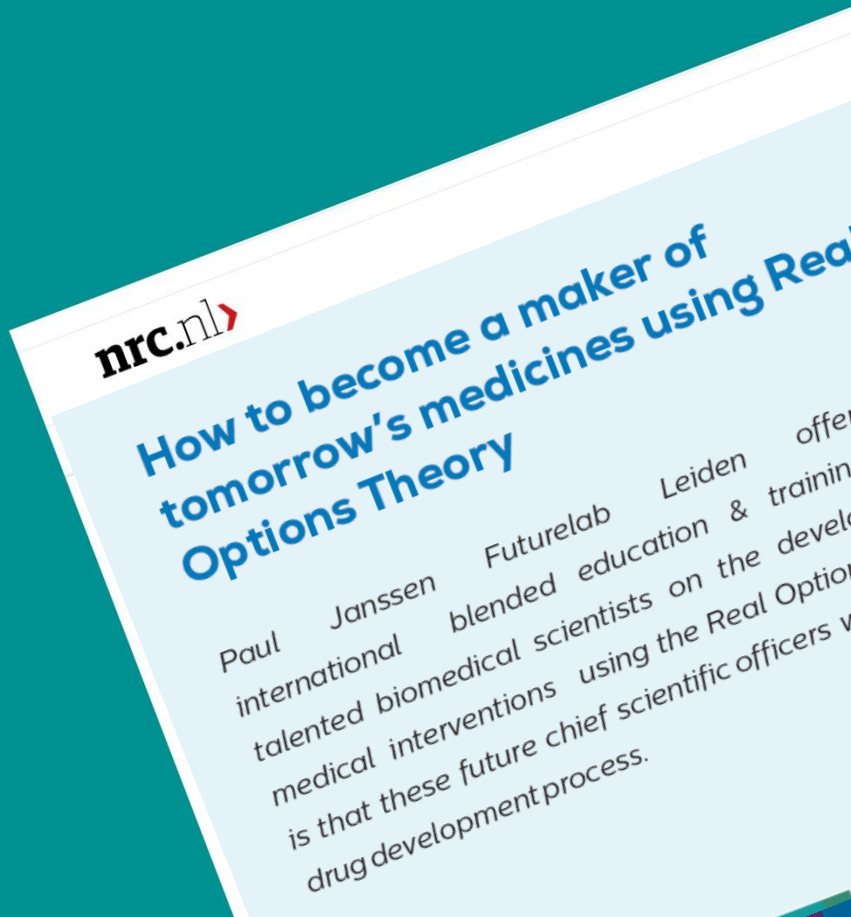
Paul Janssen as a role model for the learners of Paul Janssen Futurelab Leiden



Dr. Paul, a physician, medicinal chemist, pharmacologist, and entrepreneur.

Agreement family Janssen and the Leiden University Medical Center

How to become a maker of tomorrow's medicines?



Education is key

Education is key

Academic research project	VS	Development of intervention
Design of one clinical trial		Design of development program with multiple clinical trials
Focus is on scientific paper		Focus is on bringing product to the market and patient
Product is moving target		Product is ‘frozen‘ during the development program
Project in isolation		Integral approach
Emphasis on creativity and academic freedom		Emphasis on predetermined end points, ‘frozen’ claims and Target Product Profile

Academic (mis-)conceptions on registration procedures (1)

It's a bureaucratic process.
True! But also a systematic process to maintain order, maximize efficiency, and eliminate favoritism.

It's a very expensive process.
True! But with a rational and lean & mean approach costs can be reduced extensively.

You always need extensive non-clinical/animal data (tox & disease models)
Can be true but not necessarily!
Depends on the intervention.

You always need a placebo-controlled trial.
Can be true but not necessarily!
Depends on intervention and target population.

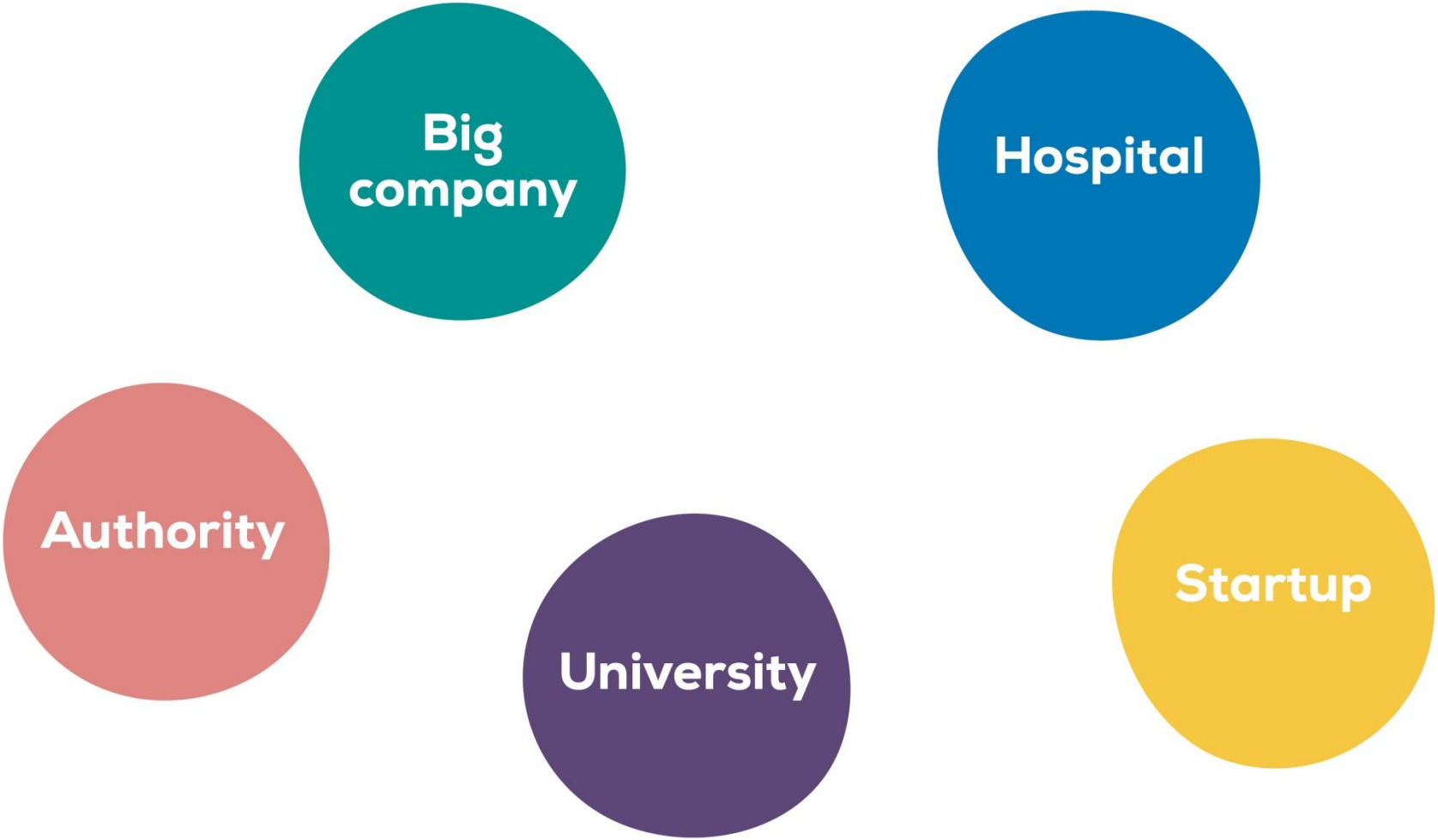
Academic (mis-)conceptions on registration procedures (2)

You need to demonstrate that the intervention is safe & effective.
Not quite! You need to demonstrate that the intervention has a positive risk/ benefit ratio within the intended use.

You need a GMP batch before you can start the non-clinical studies.
Not true!

The guidelines are mandatory and determine the research.
Not true! Guidelines are there to help you. You can deviate from the guidelines, but you need to explain why you do that.

Clinical development is a fixed linear process: Phase I > Phase II > Phase III.
Not true!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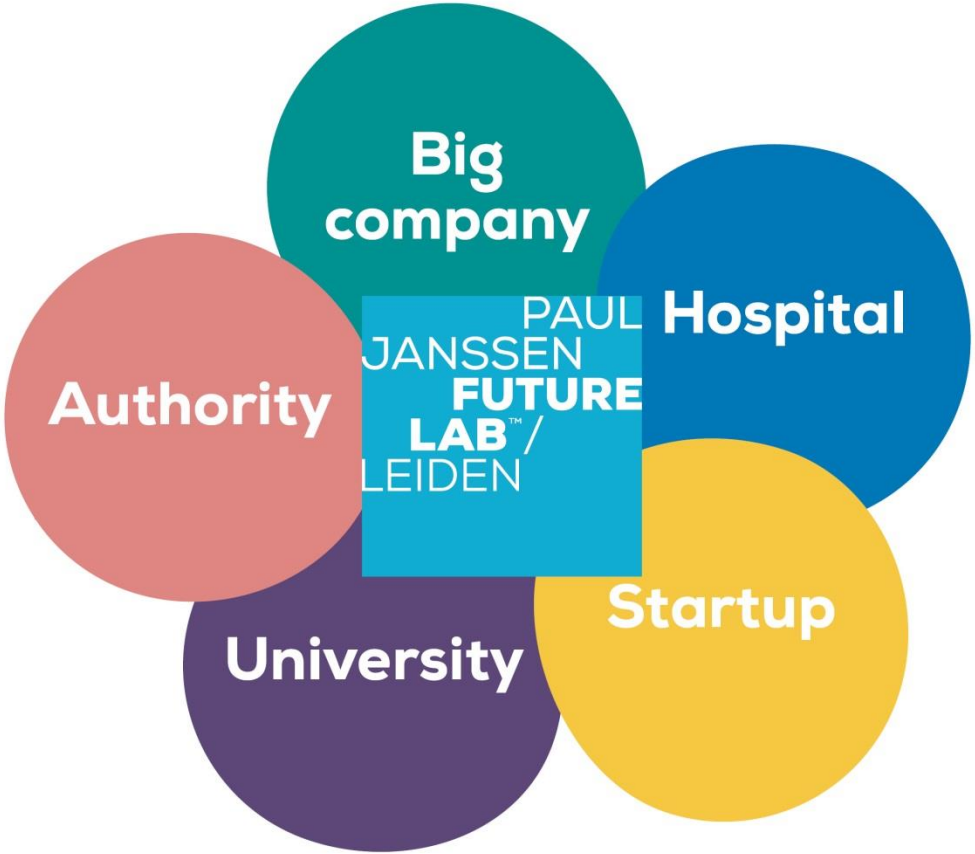
University
Startup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Hospital
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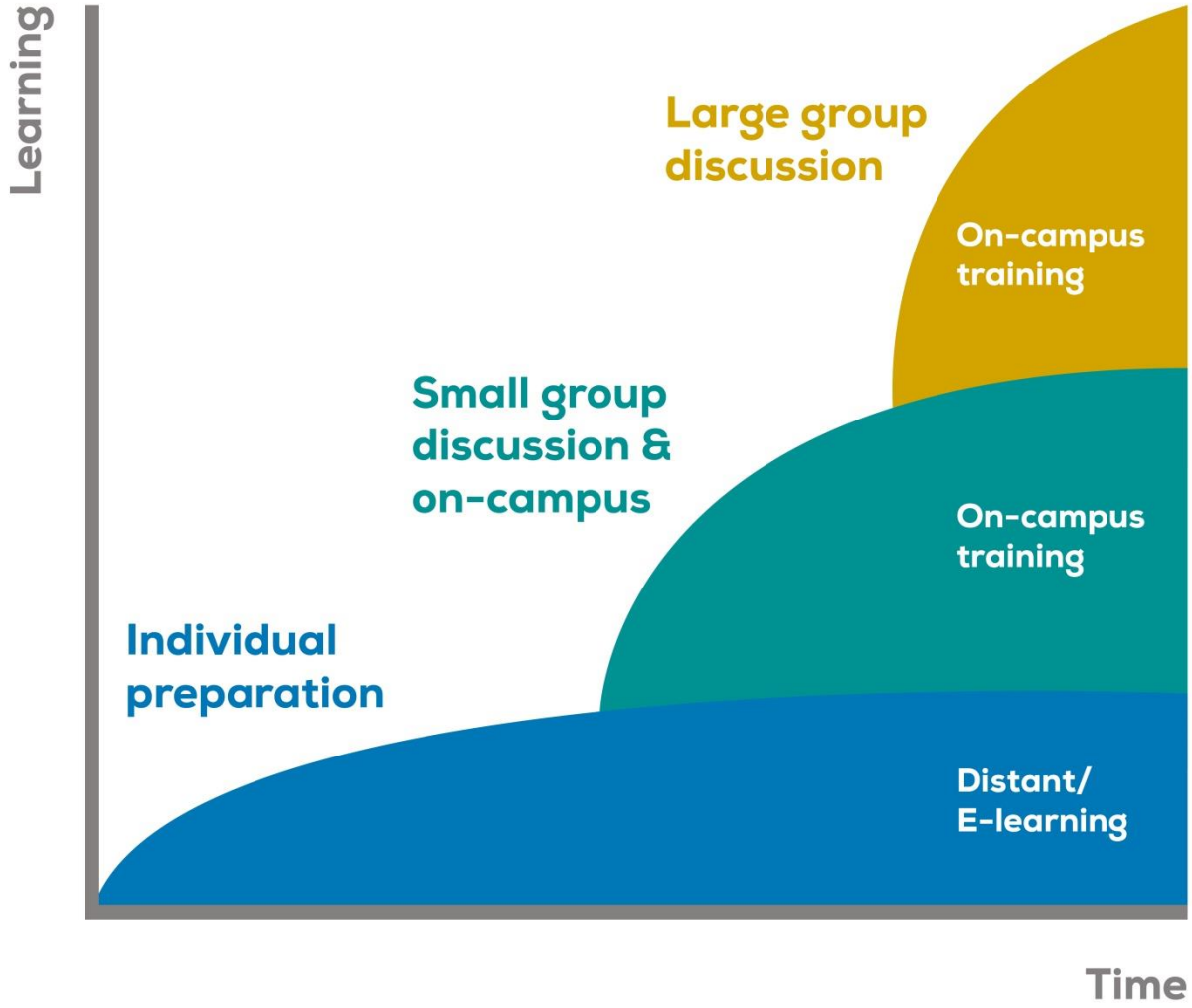
PAUL JANSSEN FUTURE LAB™ / LEIDEN
University
Startup

Three stages of the learning process using case studies



Our first module

Clinical Development
started April 3rd 2017

We just opened another window

Application Deadline **1 May 2017**

Clinical Development

Online

- 5 week online cou
- Online exa

On-cam

- urse
- xam
- 4 day On-campus

campus Extended

- 5 week online course
- Online exam
- 4 day On-campus
- 5 day On-campus extended
- Win a € 500.000 grant

Scholarships!!

On-campus course Clinical Development

using case studies such as the development of bedaquiline

Average overall score on-campus course

4.8

Average score mock EMA Scientific Advice meeting with regulators from UK and NL

4.6

scale 1-5

University Medical Centre

"I also learned a lot from the visit of the EMA, and the researcher who worked hard throughout his life to bring drugs to the market."

Pharmaceutical industry

"As I hoped, the on-campus course was great. I feel very fortunate to have worked with this group of participants since we were all very dedicated, open and sharing(with a broad background/expertise)."

Pharmaceutical industry

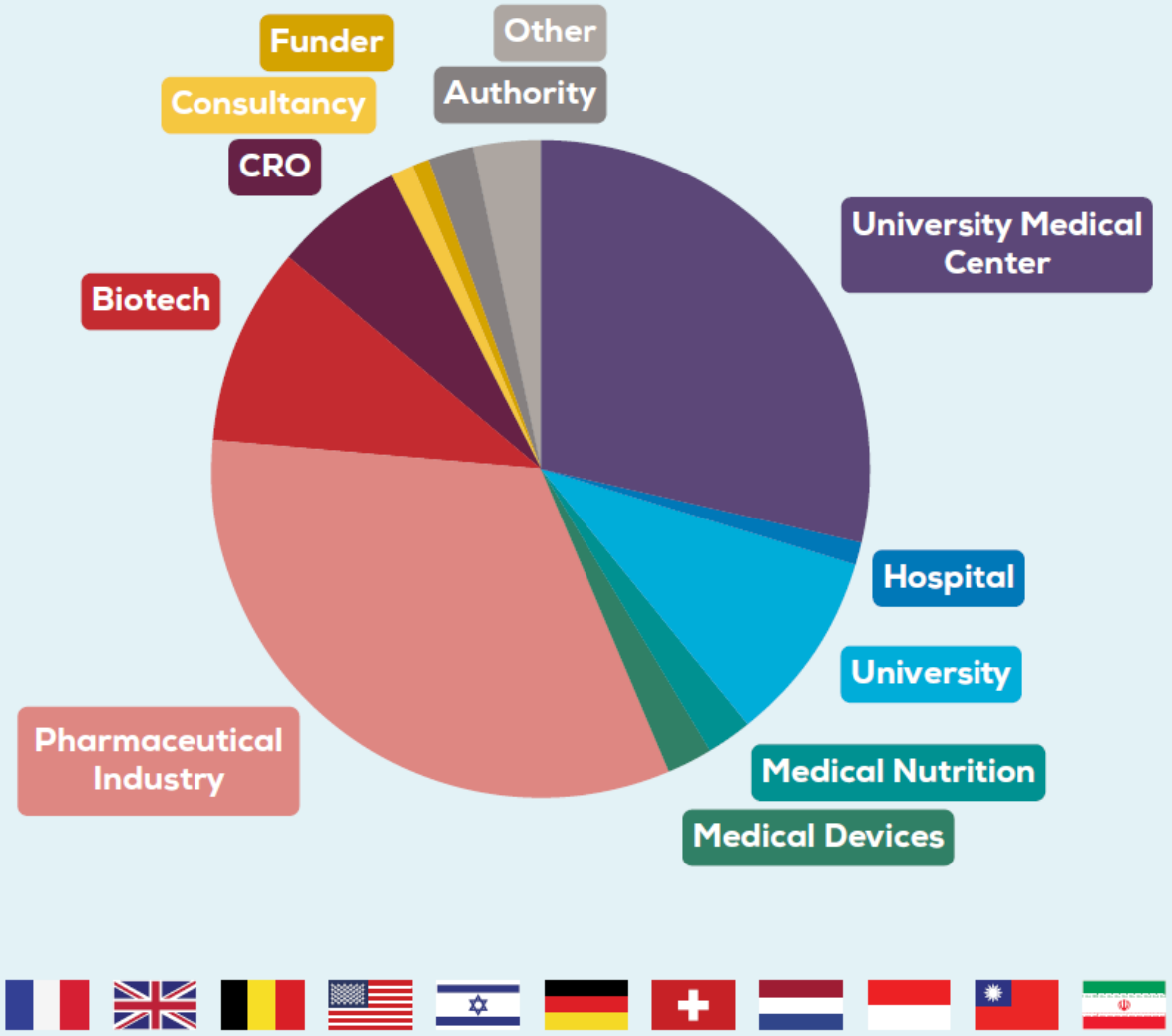
"It's very intense and exhausting, but absolutely worth it."

Pharmaceutical industry

"For someone with limited previous experience in clinical development, this course has truly increased my understanding and enthusiasm for this work field."

University Medical Centre

"Neatly organized course, great speakers, great cases. How good to learn in small groups with people with such a different background."


Funder
Other
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Authority
CRO
University Medical Center
Biotech
Hospital
University
Pharmaceutical Industry
Medical Nutrition
Medical Devices

Upcoming new blended courses from Paul Janssen Futurelab Leiden in 2018

Intellectual Property

Pharmacology

Finance

Market Approval

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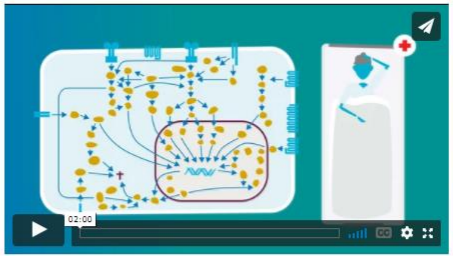
Blended learning for entrepreneurial biomedical professionals

Paul Janssen Futurelab Leiden is an international blended learning (online and on-campus) program for entrepreneurial biomedical professionals.

www.PaulJanssenFuturelab.eu

The application deadline for the scholarships has been extended to **this Thursday, April 5, 12:00 CET**

Apply now



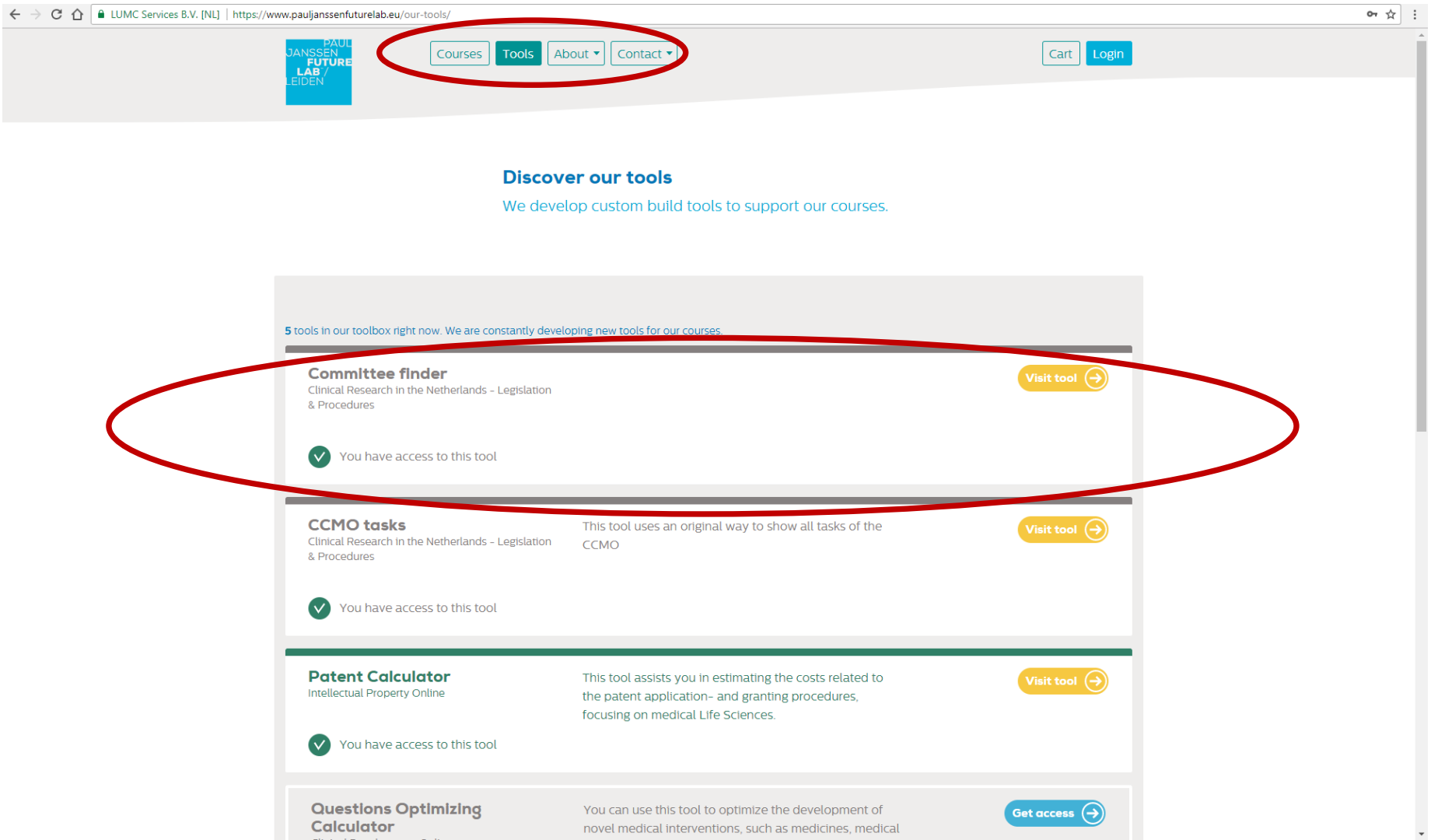
Free course theme "Mandatory Review of Medical Research" is now live

Start course

Experience the on-campus

For four days, you will further explore question-based development in the beautiful setting of the castle and hotel Oud-Poelgeest. With a small group of maximum 30 course participants, you will reside at the castle and examine teaching cases that are based on real events. In "what really happened" sessions, invited speakers discuss the actual choices that were made during the case.

Read more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5 tools in our toolbox right now. We are constantly developing new tools for our courses.
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Patent Calculator
Intellectual Property Online
This tool assists you in estimating the costs related to the patent application- and granting procedures, focusing on medical Life Sciences.
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Questions Optimizing Calculator
You can use this tool to optimize the development of novel medical interventions, such as medicines, medical
Get access

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Committee Finder

With this tool you'll find the committees, competent authorities and other organisations involved in the legal review of your clinical research proposal in the Netherlands.
Like this tool? We at Paul Janssen Futurelab created it for you. Visit us online

Start to find your committee

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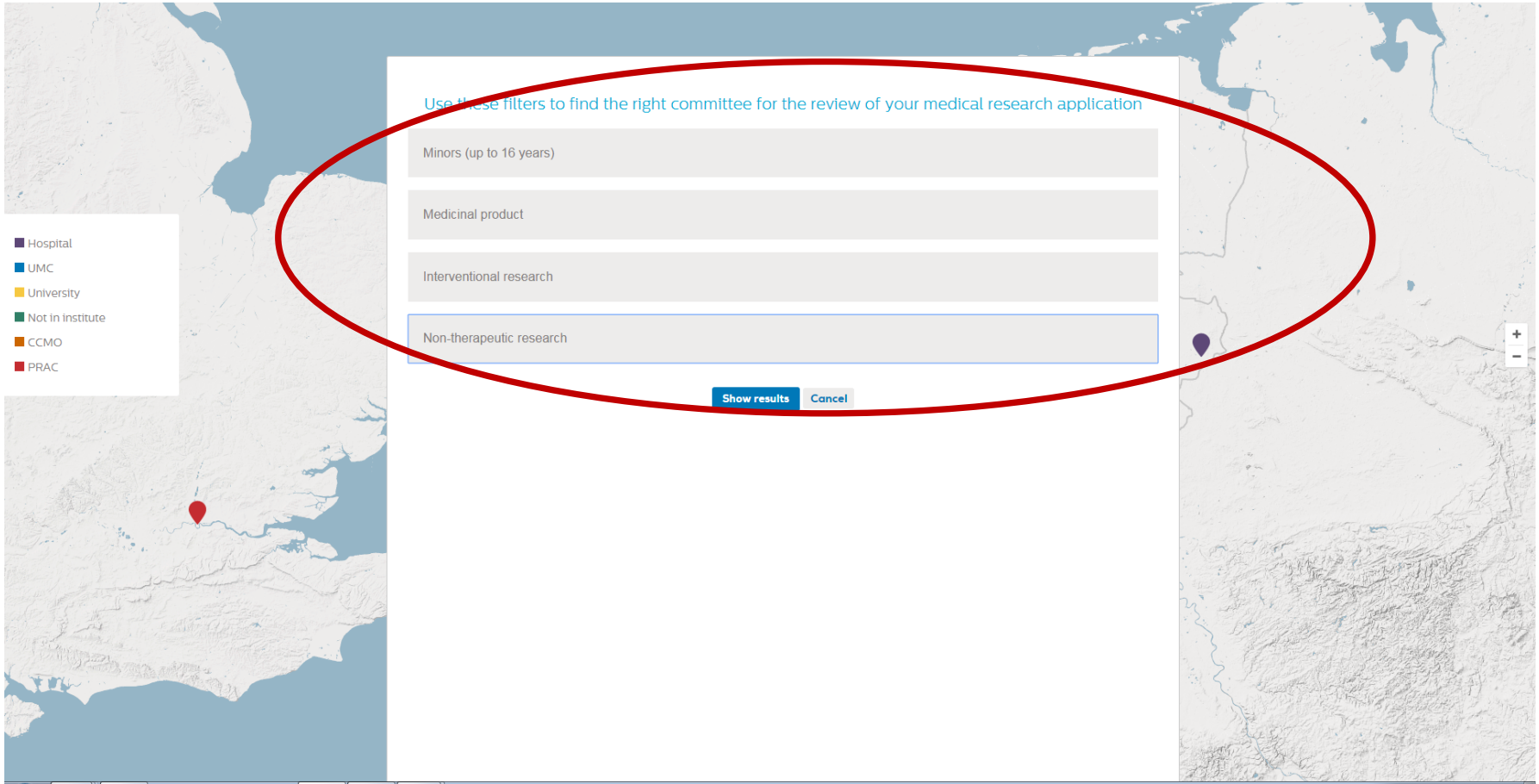

Committee Finder

You selected: Minors (up to 16 years) | Medicinal product | Interventional research | Non-therapeutic research | 1 reviewing committee

Note: This study has to be reviewed by the CCMO. The Medicines Evaluation Board (MEB; Dutch: CBG) is the competent authority.

Legal review timelines:
Research file: CCMO 60 days, MEB 14 days
Substantial amendment: CCMO & MEB 35 days

LUMC Services B.V. [NL] | https://pauljanssenfuturelab.eu/tools/clinical_research_in_the_netherlands/committee_finder/?user_id=0&token=

Committee Finder

You selected: Minors (up to 16 years) | Medicinal product | Interventional research | Therapeutic research | 19 reviewing committees

Note: This study has to be reviewed by an accredited Medical Research Ethics Committee (aMREC) with a clinical pharmacologist and a hospital pharmacists in the committee. The CCMO is the competent authority.

Legal review timelines:
Research file: aMREC 60 days, CCMO 14 days
Substantial amendment: aMREC & CCMO 35 days


If you are planning for a year, sow rice.
If you are planning for a decade, plant trees.
If you are planning for a lifetime, educate people.
Chinese proverb

CBG MEB
Medicines Evaluation Board

ccmo

CHDR

Memorandum of Understanding

LUMC Leids Universitair Medisch Centrum

Nederlandse Vereniging voor
KLINISCHE FARMACOLOGIE
en Biofarmacie

NVFG
NEDERLANDSE VERENIGING voor FARMACEUTISCHE GENEESKUNDE

See you in the future

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