

Leiden, January 2019

Subject: Janssen Pharmaceutica Scholarships for biomedical start-ups

Dear colleague,

Janssen Pharmaceutica NV has made available 2 scholarships for start-ups currently developing a product for a new medical intervention to participate in the **complete blended course Clinical Development** from Paul Janssen Futurelab Leiden. PJ Futurelab is a non-profit, independent education & training initiative of the Leiden University Medical Centre and Leiden University. Our mission is to train graduated biomedical professionals to be tomorrow's leaders in life sciences.

The 3-part Clinical Development course introduces the Question-Based Clinical Development approach to define the most optimal development pathway for new medical interventions (online course with exam) and offers participants a unique opportunity to work on extensive teaching cases based on real R&D projects in interdisciplinary groups (on-campus course). Finally, a individual mentor guides participants to write a ready-to-submit clinical trial application (on-campus extended course). Seating is limited (max 25 participants per course) to ensure the highest quality and intensive interactions. This accredited certificate course received 4.6 out of 5 stars from participants.

Eligible candidates are graduated (bio)medical professionals working in an early phase start-up which has (as yet) no clinical

Alumnus MEB-CBG

"I liked to have a 'new' insight in clinical development being a regulator and previous an academic. I really liked the 'what really happend' stories after writing my own development plan."

Alumnus Abbvie B.V.

"I think the course was excellent and exceeded my expectations! Working in groups with people of different background and experience was a very enriching experience and worked very well for this course."

Our course participants rate this course 4.6 out of 5



development program, but with concrete plans to start a first-in-man trial within 1–1.5 years. The scholarship covers the full course fee of €5600,- and gives access to the complete blended course: a 5-week online introduction course + 4 days on-campus + 5 days on-campus extended. The on-campus and on-campus extended courses are given in and near Leiden. The **application deadline is February 18, 2019, 12:00 CET**. For more information and how to apply, please visit <https://www.pauljanssenfuturelab.eu/scholarships-for-start-ups/>

With kind regards,


Marcel Kenter, PhD
Director PJ Futurelab


Bart van Zijl Langhout
Janssen The Netherlands Campus Lead

About blended learning

The blended courses are designed for working biomedical professionals who combine continued learning with a busy work and home life. We invest great time and energy into making our courses engaging and exciting. We use various learning formats, including animations, interactive self-assessment tools, expert interviews, scientific publications and teaching cases to bring across the subject matter in a concise and memorable way. Tools to aid participants during the course are also included and remain free to use for all alumni.

About the course

The online **Clinical Development course**, developed by Saco de Visser, PhD (clinical pharmacologist and instructor of this course), discusses the commonly used (risk-adjusted) Net Present Value ((r)NPV) technique and its shortcomings when valuing R&D projects. The course introduces the new Question-Based Clinical Development methodology as an alternative method that combines project valuation with the important scientific questions to define the most optimal clinical development program for your product.

In the **online course** you will learn to apply the Question-Based Clinical Development (QBCD) approach to define an efficient development pathway for new medical interventions. The online course is completed with an online exam and has a study load of approx. 5 hours/ week. The online course can be combined easily with a busy work and private life due to its flexibility and modest study-load.

“Learn the question-based clinical development method and practice with illustrative teaching cases”

“Work in small interdisciplinary teams and dive head first into a myriad of advanced teaching cases based on real-world examples”

The **on-campus course** offers in-depth teaching cases that you will work on in small, interdisciplinary teams. The teaching cases are based on real-world R&D projects and are developed in close collaboration with prominent life sciences companies. On-campus in the beautiful setting of Castle Oud-Poelgeest, you will meet like-minded peers from industry and academia and invited speakers who were involved in the R&D projects of the teaching cases. This course requires full time availability

during 4 days in Oegstgeest (near Leiden) and requires approximately 20 hours preparation time for readings and pre-course assignments.

During the **on-campus extended course** you will develop your own idea for a first-in-man study into a clinical protocol with the guidance of a clinical expert. At the end of the 5-day on-campus extended course, you will have a ready-to-submit clinical trial application. Application for this course requires submission of a short summary of your proposed first-in-man trial. Your full time availability is required during the course and working spaces are offered by CHDR, but most work during this course will be done on a (flexible) individual basis.

“Work with a mentor - a clinical expert - to develop your own clinical trial and guide you through the challenges of drafting a clinical trial application”

About PJ Futurelab

Paul Janssen Futurelab Leiden is a new, non-profit initiative of LUMC that offers education and training programs for entrepreneurial (bio)medical professionals. PJ Futurelab collaborates with Centre for Human Drug Research (CHDR) and several life sciences companies, academic institutes and regulatory authorities (J&J, Hoffmann-La Roche, Sanofi Genzyme, Medtronic, CCMO, EMA and others). **Our mission** is to train ambitious (bio)medical researchers to be tomorrow's leaders in the discovery and development of novel medical interventions (e.g. medicinal products, medical devices, medical nutritional products). New courses **Pharmacology**, **Intellectual Property** and **Market Approval** are currently being developed. Visit the website for more information about our courses.

See you in the future

www.pauljanssenfuturelab.eu

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