

## Expert Class about Clinical Trials and Regulatory Affairs

### Invitation for Startups in LifeSciences and Medical Technology

When Friday 29 March 2019 | 12:00 – 18:00 hrs

Where Pivot Park Meeting centre in the Chesbrough building Kloosterstraat 9, Oss  
Pivot Park is a life sciences campus, with a special focus on pharmaceutical innovation.



#### Dedicated Expert Classes | highly valuable to attend

We sure hope to welcome you (again) at the [LifeSciences@Work Accelerator Expert Class](#). We, team LS@W, together with our contributing experts, will offer you a practical insight into important steps to take when establishing your startup. The setting of the Expert Classes is small scale and informal. Participation is free of charge, provided you match our profile.

#### Expert Class Features

- **Expert lectures:** Listen, learn and ask. Presentations by renowned professionals
- **Startup experiences:** how did it all begin/funding/operations/where are they now/tips
- **Speed sparring:** all participants will take part in addressing business questions either on the Expert Class topic or on entrepreneurship in general.
- **Networking:** Create (more) visibility for yourself and for your venture, connect and engage.

**Let us guide you in the right direction!**



## Expert Class | Clinical Trials

Programme 29 March 2019

**Clinical Trials:** Getting a clinical trial underway is no simple task. From patient recruitment to study completion, the drug maker or med tech developer must undertake a wide array of complex, and closely monitored operations, complying with regulations all the way. Trials become more global, patient groups more targeted, and investigator sites more widespread. Where to begin and how to set it up?

Closely connected with Clinical Trials are Regulatory Affairs: The final hurdle – getting your drug, therapy or medical device approved and on the market. Talk with experts about the regulatory requirements in Europe and the rest of the world, since they are continually evolving and vary from one country to another. What does it take to navigating through the different regulatory landscapes?

### Experts

#### Introduction

- **Pivot Park – Rick Meurders, Business Development Manager**  
Offering lab and office space of any size with access to high-quality pharmaceutical R&D facilities and infrastructure and expertise.

#### The big picture

- **3DPharmXchange – Ronald van der Geest, Partner**  
Dedicated to the development of pharmaceuticals and diagnostics; providing all core expertise needed to take a drug development program from A to B or from A to Z, if required.

#### The academic perspective

- **Radboudumc Technology Center – Jaqueline Droste, Manager Radboudumc Technology Center Clinical Studies Policy Quality and Support**  
Optimally facilitating clinical research. In the Technology Center knowledge, expertise and capacity for conducting clinical studies and scientific research merge.

#### Expert cases

- **Xeltis – Luc Verhees, SVP Clinical, Medical and Pre-clinical affairs at Xeltis**  
Xeltis is a clinical-stage medical device company pioneering a restorative approach in heart valve therapy. RestoreX, Xeltis technology platform, is the world's first polymer-based technology designed to enable natural restoration of heart valve function, through a therapeutic approach called Endogenous Tissue Restoration (ETR).
- **Company contribution**
  - SME: in contact Atro Medical and/or
  - Big Parma: in contact with MSD, Amgen



## Expert Class | Health Technology Assessment & Reimbursement

### Speed Sparring

All participants will take part in addressing business questions either on the Expert Class topic or other.



### About the L@SW Expert Classes

LS@W Expert Classes are a series of targeted workshops organized in close collaboration with industry experts on relevant topics for Life Sciences and Medical Technologies Startups. These small-scale Expert Classes are specially organized for alumni and participants of the Venture Challenge, Value Centre, MedtechPartners, BiotechPartner and Take off and are free of charge.

### Registration

Send an email to Ellen de Waal: [dewaal@lifesciencesatwork.nl](mailto:dewaal@lifesciencesatwork.nl), adding the following details: First name – suffix -last name - email - phone and/or cell phone; Name of startup - status startup - stage of your startup; Questions for the experts. Note: Startups not (yet) part of our LS@W community but who are interested to join are welcome provided you match our community profile.

We thank our 2017/2018 contributing Experts from:

[IXA Amsterdam](#), [Amsterdam UMC-University of Amsterdam](#), [Agendia](#), [Sanofi](#), [CbusineZ](#), [Loyens & Loeff](#), [YesDelft](#), [TU Delft/Delft Enterprises](#), [NLO](#), [European Patent and Trademark Attorneys](#), [DSM Global Business Incubator](#), [TU/E Innovation Lab](#), [Usono](#), [Philips](#), [M Ventures](#), [RVO](#), [Merck Ventures](#), [2-BBB](#), [Aglaia BioMedical Ventures](#), [Netherlands Enterprise Agency \(RVO\)](#), [BioGeneration Ventures](#), [Kite Pharma EU](#), [Netherlands Cancer Institute – Antoni van Leeuwenhoek Hospital](#), [Axon](#), [eNoviTe](#), [Thuja Capital](#), [Technology Transfer Office](#), [Erasmus MC](#), [European Patent Office](#), [InnovationQuarter](#), [Luris](#), [BioPartner Leiden](#), [PSR Orphan Experts](#), [Paul Janssen Futurelab Leiden](#), [Utrecht Holding](#), [MDxHealth](#), [Julius Center THINC](#), [UMC Utrecht](#), [Vereniging Innovatieve Geneesmiddelen](#), [UMotion](#), [Sciences Affairs](#).

### About the LifeSciences@Work Accelerator

LifeSciences@Work – since 2008 - is the national accelerator for high potential start-ups in Life Sciences and Medical Technologies. We offer a customized programme to help innovators build their business: [The Venture Challenge](#), [Expert Classes](#), [the Value Center](#). Powered by Heath-Holland, Top Sector Life Sciences & Health, Laan van Nieuw Oost-Indië 334, 2593 CE The Hague, The Netherlands

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