lifesciences@work

Health~Holland

Expert Class

Health Technology Assessment and Reimbursement

Programme • Information

When Friday 15 February 2019 | 12:00 – 18:00 hrs

Where Amsterdam Medical Center | Meibergdreef 9, Amsterdam | Vrijzaal (G 0-2015)

Hosted by INNOVATION EXCHANGE AMSTERDAM

Let us guide you in the right direction!

Date

- **15 February 2019**

Time Frame

- Starting at 12:00 hrs – ending at 18:00 hrs

Venue

- Amsterdam Medical Center (AMC) | Meidelbergdreef 9, 1105 AZ Amsterdam | Vrijzaal (G 0-2015)

Audience

- Exclusively organized for Venture Challenge, Value Voucher, Medtech Partners, Biotech Partners, Take Off Alumni and new life sciences and medical technology startups

Topics

- Health Technology: any aspect of healthcare and includes Diagnostic, Medical Devices, Drugs, Therapies, Medical Procedures, Prevention programmes etc.
  Health Technology Assessment (HTA): policy research that examines the short and long-term consequences of using a healthcare technology. It is a multidisciplinary process that summarizes information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Where there is a lack of data, HTA can be used to generate information. HTA is not only relevant to Europe: it has been used by healthcare providers across the world, and its use is increasing. HTA processes varies from country to country – even within countries.
- Closely linked to HTA is reimbursement. Health insurers are not automatically allowed to provide cover for any new medicine that comes onto the market. Governments decide what drugs fall under the standard health insurance package.

Programme Features

- Presentations and personal experiences by renowned expert
- Speed Sparring and free 1-on-1 consultations
- Networking and making valuable mutual introductions

Save this date

- Expert Class | 29 March 2019 | Clinical Trials & Regulatory Affairs | Pivot Park, Oss

Thank You!

Contributing Experts and Supporting Organisations

Programme & Contributing Experts

12:00 – 12:30 hrs. Ready to welcome our participants with lunch

12:30 – 13:30 **Welcome & Who's who**

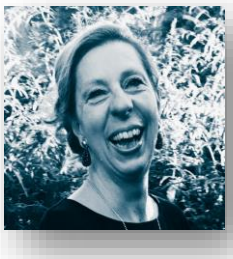
Ellen de Waal
Partner | LifeSciences@Work Accelerator, Science Affairs
Owner Sience Affairs, since 2015 | Owner Publimarket 1989-2014
Communication Manager, IMI HARMONY Alliance | European Centre of Excellence for big data in Hematology

Innovation through collaboration

Michelle Meeks
Business Developer MedTech, Innovation Exchange Amsterdam (IXA)
Amsterdam UMC – location AMC

13:30 – 14:45 **Expert Lectures & Interaction**

HTA Perspective from an academic institution



Corianne de Borgie
Head Clinical Methodology of clinical research
Amsterdam UMC - University of Amsterdam

Reimbursement – Perspective from a 'paying' organisation

Jeroen Nugteren
Business Manager
CbusineZ

Programme & Contributing Experts | continued

14:45 – 15:15 Break | Speed Sparring

15:15 – 16:30 **Expert Lectures | Interaction**

Perspective from a biotech company

Sari Neijenhuis
Agendia, Medical Director EU

The role of HTA in patient access to innovative medicines
Perspective from a pharmaceutical company

Lars Wormhoudt
Sanofi, Head market access NL

16:30 – 17:15 Speed Sparring

17:15 – 18:00 Wrap-up | Networking | Space for 1-on-1 consulting | Drinks

Speed Sparring

The Sparring sessions will take place during the breaks in 2 x 2 sessions of 10 minutes each.

- Round 1: from 14:50 – 15:00
- *5 minute switch*
- Round 2: from 15:05 – 15:15

- Round 3: from 16:40 – 16:50
- 5 minute switch
- Round 4: from 16:55 – 17:05

Participating Startup Teams | in alphabetical order by company/organization name

CC Diagnostics | https://cc-diagnostics.com/

Arnoud Huisman

In the western world, 10 million triage tests are performed in cervical cancer screening programs on an annual basis. In Europe, almost one million women are falsely diagnosed with having cervical cancer with the use of today's available tests. This leads to an annual financial burden of €360 million per year for the European society and severe psychological distress for the woman. Implementation of the CC Diagnostics' methylation assay will decrease the number of false positives with 33%. As a result, we will save >€120 million of annual healthcare cost for the European society and prevent unneeded emotional stress for thousands of women.
CC Diagnostics collaborates with the research group of the UMCG. During 15 years of research, this group has identified unique tumor-suppressor genes. Small-scale validation of the best combination of genes show, using the methylation assay as a triage test, an 81% specificity and a 50% increase in reproducibility, which outperforms any triage test available, regardless which primary test has been used. CC Diagnostics will, in collaboration with the UMCG, validate this combination in a large-scale study with 3600 samples; results of this study are expected Q4 2019. CC Diagnostics holds an exclusive worldwide license on the patent.

Daidalos Solutions | www.daidalos-solutions.com/

Eric Berreklauw

Daidalos ontwikkelt medische implantaten, voornamelijk op het gebied van de cardiologie, hartchirurgie and vaatchirurgie. Opgericht door Dr. Eric Berreklouw, een Nederlandse hartchirurg met bijna 40 jaar klinische ervaring, en ontwikkelt medische implantaten, voornamelijk op het gebied van de cardiologie, hartchirurgie en vaatchirurgie. De meeste producten zijn gemaakt van Nitinol geheugen metaal, en worden uitvoerig invitro en ex-vivo getest voor bij mensen toegepast. Het bedrijf verzorgt in samenwerking met een netwerk van medische specialisten, internationale Europese en Amerikaanse bedrijven de product ontwikkeling, IP bescherming, design, prototyping, testen van haar producten. Afhankelijk van het type product worden de producten vermarkt middels eigen productie en verkoop, of middels licentie-overeenkomsten. Producten van Daidalos Solutions zijn onder meer hechtingloze hartkleppen, hartklep vernauwingsringen, vaatconnectoren, weefselvernauwers en afsluiters, en werkkanalen naar het hart en vaten. Alle producten hebben unieke eigenschappen die hen onderscheiden van concurrerende producten en zijn gericht op minimaal invasieve toepassing en gebruik van operatie robots.

ExoVectory | http://exovectory.mobirisesite.com/

Jetty van Ginkel

Glioblastoma is the most aggressive type of brain cancer. The standard of care gives an extended life span of merely 18 months. Highly promising gene therapies are being developed for this group of patients, however widespread delivery into the tumor is not achieved and migrated tumor cells are not reached.
ExoVectory offers a platform technology to produce large DNA constructs tightly packaged into naturally secreted human exosomes. Exosomes are invisible to the immune system and can travel to migrated or metastasized areas. ExoVectory's loaded exosomes show widespread delivery in 3D cultured tumor cells and demonstrate efficient spread through mouse brain. We will combine ExoVectory's packaging system with therapeutic transgenes to create a novel therapy for glioblastoma.
ExoVectory will require an initial investment of € 1 million to reach in vivo proof of concept, followed by an additional € 1.5 million to get the product ready for a phase I/II clinical trial. The total budget required to prepare our product for out-licensing is expected to remain under € 7 million. The income generated through out-licensing will feed into the further development of ExoVectory's platform technology.

Inventin | http://inventin.nl/

Corne van den Kieboom

Inventin believes in the strength of collective knowledge. We give preference to call on a dedicated specialist to accelerate and enhance the quality of development. Our core knowledge is porting relevant in vitro diagnostics to innovative detection assays and platforms. From co-developing hardware, sample preparation to clinical validation of in vitro diagnostics, Inventin carries a well-rounded portfolio. Not shying away from a challenge, we strive to improve in vitro diagnostics together with you. We have many years of experience developing in vitro diagnostics on location. This carries great benefits for our customers as research and development will take place in your trusted environment or specialized centers. Our core knowledge concerns the development of sample preparation and detection assays for in vitro diagnostics with the sole purpose to port these protocols to innovative diagnostic platforms. Furthermore, we maintain a vast network of dedicated researchers and clinical specialists. All to provide the most effective and efficient solution for your need. Inventin is also experienced in developing prototypes for a broad range of applications, from in vitro diagnostics to laboratory equipment.

MarkMyGenes | www.lifesciencesatwork.nl/profile/markmygenes/

Wouter de Jonge

MMG's mission is to develop and commercialize predictive screening tools for optimal therapeutic strategy for chronic inflammatory disease, and provide concrete measures for personalized medicine for every patient in need.
MMG aims to bring an epigenetic marker kit to the market, which will help doctors and thus patients to choose the right therapeutic option predicting the highest success rate, based on their epigenetic profile. Instead of going through a potentially long and expensive period of searching for the optimal treatment, MMG can help both patient and doctor to decide which biological will provide the best response. The kit's use will lead to multiple benefits since patients are receiving a tailored approach; leading to enhanced therapeutic efficacy and lowering cost for the healthcare sector as a whole.

Medcore Health | https://medcorehealth.nl/

Tim Bruines
Diederik Rasenberg

Due to sterility, surgeons cannot directly interact with the digital systems around them during procedures. This means one of the assistants outside the sterile zone has to drop their work to control the terminal on behalf of the surgeon when requested.
Every time a surgeon needs to interact with a digital device creates an intermission, adding up to time and focus loss. The need for an assistant to control the digital systems also decreases the possibilities for equipment manufacturers to make their products more usable and interactive. This also causes more than half of the functionality of most OR devices to be non-viable for use during procedures.
Lack of a good control method also results in inefficient use of supporting OR personnel, which is currently in short supply resulting in OR vacancy of up to 25% in larger hospitals.
After a process with frequent clinical input, we have designed a digital OR workspace that allows surgeons to control digital systems with hand gestures. This is realised by combining existing motion-tracking hardware with our OR dashboard software overlay. By further developing and implementing this product and corresponding service, we will: Reduce procedure, Improve OR team atmosphere, Allow new/enhanced activities during surgery and improve supporting personnel efficiency, increasing the amount of procedures that can be carried out per day.

NeoStartTrack | www.lifesciencesatwork.nl/profile/neostarttrack/

Oda Heerema

Being born is the most challenging event mankind will experience. 10% of newborns do not breath. Because of oxygen shortage 7% of this group will face disability for the rest of the life and 7% will die. NeoStartTrack will safe lives and costs for society. Professional support in the first 5 minutes of life is crucial to avoid oxygen shortage. Technically it is complicated to provide adequate ventilation. No adequate feedback on actions is available with conventional equipment. Guidelines prescribe, in addition to a conventional stethoscope, to use oxygen saturation bands and ECG patches to obtain objective and numeric information about ventilation and heart rate. It takes on average 90 seconds to get a reliable signal from ECG measurement at newborns. Oxygen saturation is not a valuable parameter in the first 10 minutes. These devices do not give feedback on ventilation efforts, while this is key to improve oxygenation.
NeoStartTrack is an innovative medical device that will give instant feedback on ventilation effectiveness and heart rate range. This enables direct and adequate adaptation of treatment. Due to smart sensor technology supported with state-of-the-art algorithms, NeoStartTrack provides an instant and reliable signal on ventilation and heart frequency.

Sagacity | www.sagacity-pharma.com/

Karen Malone

Sagacity is focused on developing drugs for the prevention of Alzheimer's Disease. This requires a safe drug that gets to the brain and is of low burden to patients in terms of both cost and application. In our primary drug development program, small molecules blocking Tau aggregation will be optimized to lead stage. Upon development of our lead compounds, we will enter pre-clinical development, becoming investor-ready for more significant funding to complete Phase I/II studies in healthy persons at high risk of AD, as defined by biomarkers. Using a proprietary assay to screen the J&J compound library, we have obtained first-line hits, giving us the green light to proceed with our large-scale screen. At this time, we are working with J&J to spin out this early phase program, that will serve as the cornerstone of our portfolio.
In our primary drug development program for Tau aggregation inhibitors, compounds will be optimized to lead stage. Upon selection of our lead compounds, we will enter pre-clinical development, becoming investor-ready for more significant funding to complete Phase I/II studies in healthy persons at high risk of AD, as defined by biomarkers. To reach our next developmental milestone – completion of the hit-to-lead optimization- an investment of 600.000 is needed.

Sensius | www.sensius.biz

Paul van den Biggelaar

Sensius offers a complete solution to administer deep thermotherapy for the head and neck region. The solution is based on the Hypercollar3D technology from Erasmus Medical Center Cancer Center. Development started more than 10 years ago and several dozens of patients have been treated with the Hypercollar and the Hypercollar3D. A key element in the design of the HyperCollar3D is to control SAR in virtually all regions of the full head & neck area. Organs at risk like the spinal cord, eyes and other areas can be properly protected against hotspots through its smart placement and control of antenna power. The Hypercollar3D solution treatment is fully supported by software planning and control during treatment delivery. This level of planning enables the radiation-oncologist to set specific treatment objectives and minimize undesired side effects. During treatment, near-realtime adaptation of the plan is possible based on measurements and patient feedback. Treatment interruption is minimized. The horseshoe shape of the applicator ensures patient comfort and facilitates patient setup and easy evacuation after treatment.
The HyperCollar3D comes with full software support. Valerio Fortunati, winner of the STW "Simon Stevin gezel" award 2016 explains: "Using the tool improves the clinical routine: not only by speeding up the process of modelling, but also by having a more precise and more consistent model over all patients". Thanks to the supporting software, treatment is reliable and reproducible. Physicians can accurately control dose and will be confident about the way the patient will be treated.

Skyline DX | www.skylinedx.com

Árjan van Marel

The discovery of clinically applicable gene signatures from cancer cells in Acute Myeloid Leukemia (AML) patients led to the founding of Skyline Diagnostics in 2005. The investigators and clinicians of the Departments of Hematology and Bioinformatics of the Erasmus MC, among whom Chief Scientific Officer professor Bob Löwenberg, teamed up with biotech entrepreneur Henk Viëtor, PhD to develop that discovery into a powerful clinical tool: the AMLprofiler. Since its inception, the company has perfected and launched the AMLprofiler and filled its pipeline with other, promising new Profilers, including the MMprofiler for Multiple Myeloma prognostics. Through an innovative combination of life sciences and sophisticated information technology we turn personalised cancer treatment into reality by translating scientific knowledge into state-of-the-art clinical diagnostics.
Skyline is a privately owned company, boasting a highly experienced management team and professional life science investors. In recent years, we expanded to become a company of 25 ambitious people motivated to make personalised medicine a reality in oncology.

UpyTher | www.lifesciencesatwork.nl/profile/upyther/

Peter Paul Fransen
Geert van Almen

UPyTher develops custom drug delivery solutions for conventional and next generation therapeutics. Our lead indication will revolutionize the treatment of peritoneal cancer, which is one of the deadliest cancers and affects hundreds of thousands of patients worldwide. Aggressive hyperthermic intraperitoneal chemotherapy (HIPEC) is considered standard of care, but is also associated with poor therapeutic efficacy because it only allows short exposure to the drug. UPyTher offers a single shot therapy for peritoneal cancer that allows local continuous drug exposure to improve therapeutic efficacy, patient recovery and survival. Our platform is based on proprietary supramolecular polymer chemistry and consists of a modular hydrogel drug depot and a common chemotherapeutic drug. The unique features of this platform enable local therapy, prolonged release of a hydrophilic drug with enhanced tumor penetration, whereas comparable hydrogels for local drug delivery typically lack this combination. Moreover, our versatile hydrogel platform is compatible with various types of therapeutics including small molecule drugs and biologics. This has been shown in preclinical models of cardiac and renal disease and demonstrates the unrivalled potential of this technology for future expansion towards other indications.

Viewpoint | www.viewpoint-medical.com

Ben Palmer
Georgia Lee
Joy Hooft Graafland

Viewpoint Medical is developing a device that medical staff can carry in their pocket and use when they need to see difficult veins. The portable device attaches to a light-weight stand for hands free use. It is positioned above the access site and projects an image of the underlying veins onto the surface of the skin. Visualisation increases success rates, reducing the time and pain associated with venipuncture procedures. (completed the YES!Delft Validation Lab in conjunction with EIT Health / registered Dutch company).

Also joining | in alphabetical order by company/organization name

IXA | Wim Meijberg, Marc Roelofs

Innovation Exchange Amsterdam (IXA) is the expert interface between Amsterdam-based academic institutions and parties interested in their research findings and knowledge, such as companies, educational institutions, investors, health care providers, entrepreneurs, government bodies and societal organisations. Being an interface, IXA deploys its expertise in both directions: assisting researchers in generating societal and economic impact from their work and assisting external parties in navigating the academic landscape to find a solution or spot an opportunity.

IXA is a collaboration between the TTOs (Technology Transfer Offices) of five institutions:

- Amsterdam University Medical Centres
- University of Amsterdam (UvA)
- Amsterdam University of Applied Sciences (HvA)
- Vrije Universiteit Amsterdam

LifeSciences@Work Accelerator | Chretien Herben

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

Loyens & Loeff | Bas Megens

As a leading firm, Loyens & Loeff is the logical choice for a legal and tax partner if you do business in or from the Netherlands, Belgium, Luxembourg and Switzerland, our home markets. You can count on personal advice from any of our 900 advisers based in one of our offices in the Benelux and Switzerland or in key financial centres around the world. Thanks to our full-service practice, specific sector experience and thorough understanding of the market, our advisers comprehend exactly what you need. Keywords: Full-service practice; Legal and tax advice second to none; Independent with an international scope; Innovative and pragmatic; Focused and engaged.

Also joining | continued

Panaxea | Nick Guldenmond

Panaxea supports decision making in healthcare by assessing the relative advantage of healthcare innovations. Our clients include patients, health and life science innovators and investors, health technology adopters, public and private payers, and policymakers.

Progress EXS | Thijs Veerman

Progress-Executive Services (EXS) understands your challenges with license-to-operate and time-to-market needs. We support you by offering excellent solutions for sustainable and successful growth of your pharmaceutical business.

Center for Development and Innovation | University Medical Center Groningen (UMCG) | Elena Merlo

UMCG's Center for Development and Innovation (CDI) is the department that supports and drives societal and economic impact of UMCG expertise, knowledge and facilities. UMCG harbors a realm of highly skilled specialists, renowned scientists, state of the art equipment, dedicated laboratory facilities and, of course, devoted patient care. CDI supports the interaction between specialists, scientists, departments and collaborating parties and has both an external and internal focus.

Utrecht Holdings | Genoveva Heldens

Utrecht Holdings is the Knowledge Transfer Office (KTO) of Utrecht University and University Medical Center Utrecht. We are focused on the utilisation and commercialisation of academic research. We support scientists in creating, building and investing in innovations with a particular expertise in biotech, medtech, education and ICT.

Overview Participants | in alphabetical order by last name

Geert	van	**Almen**	**UphyTher**	www.lifesciencesatwork.nl/profile/upyther/
Eric		**Berreklauw**	**Daidalos Solutions**	www.daidalos-solutions.com/
Paul	van den	**Biggelaar**	**Sensius**	www.sensius.biz
Corianne	de	**Borgie**	**AMC**	www.amc.nl
Tim		**Bruines**	**Medcore Health**	medcorehealth.nl/
Henk	van	**Doren**	**IXA**	www.ixa.nl/en/home.html
Peter Paul		**Fransen**	**UphyTher**	www.lifesciencesatwork.nl/profile/upyther/
Jetty	van	**Ginkel**	**ExoVectory**	exovectory.mobirisesite.com/
Nick		**Guldenmond**	**Panaxea**	panaxea.eu/
Oda		**Heerema**	**NeoStartTrack**	www.lifesciencesatwork.nl/profile/neostarttrack/
Genoveva		**Heldens**	**Utrecht Holdings**	utrechtholdings.nl/
Chretien		**Herben**	**LS@W | Health Holland**	www.lifesciencesatwork.nl/
Joy		**Hooft Graafland**	**Viewpoint**	www.viewpoint-medical.com

Overview Participants | continued

Arnoud Huisman		**Huisman**	**CC Diagnostics**	cc-diagnostics.com/
Wouter	de	**Jonge**	**MarkMyGenes**	www.lifesciencesatwork.nl/profile/markmygenes/
Corne	van den	**Kieboom**	**Inventin**	inventin.nl/
Georgia		**Lee**	**Viewpoint**	www.viewpoint-medical.com
Karen		**Malone**	**Sagacity**	www.sagacity-pharma.com/
Árjan	van	**Marel**	**Skyline DX**	www.skylinedx.com/home
Michelle		**Meeks**	**IXA**	www.ixa.nl/en/home.html
Bas		**Megens**	**Loyens & Loeff**	www.loyensloeff.com/en-us/home
Wim		**Meijberg**	**IXA**	www.ixa.nl/en/home.html
Elena		**Merlo**	**UMCG**	www.biomarkerbay.com
Sari		**Neijenhuis**	**Agendia**	www.agendia.com/
Jeroen		**Nugteren**	**CbusineZ**	cbusinez.nl/
Ben		**Palmer**	**Viewpoint**	www.viewpoint-medical.com
Diederik		**Rasenberg**	**Medcore Health**	medcorehealth.nl/

Overview Participants | continued

Marc		**Roelofs**	**IXA**	www.ixa.nl/en/home.html
Thijs		**Veerman**	**Progress EXS**	www.progress-exs.com/
Ellen	de	**Waal**	**LS@W | Science Affairs**	www.lifesciencesatwork.nl/
Lars		**Wormhoudt**	**Sanofi**	www.sanofi.nl/

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. Expert Classes also offers 1-on-1 consultations with Mentors and LS@W Alumni to help you out, by sharing their expertise.

Expert classes are specially organized for alumni and participants of the Venture Challenge, Value Centre, MedtechPartners, BiotechPartner, MBI Life Sciences &Health, BioBusiness Summerschool and Take off participants. Startups not (yet) part of our LS@W community but who are interested in participating can send in a request to Ellen de Waal.

Save this date | **29 March 2019** | Clinical Trials & Regulatory Affairs, Pivot Park, Nijmegen.

We thank our 2017/2018 contributing Experts from:
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

www.lifesciencesatwork.nl | www.health-holland.com

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Become a member of our LinkedIn Group: LifeSciences@Work Accelerator