

October 14th
2021



FLANDERS VACCINE'S ANNUAL CONFERENCE

IMMUNITY FOR HEALTH

Animal models and alternatives
for the development of vaccines



A catalyst for public-private partnerships in immunotherapy and vaccine related innovations

The primary mission of Flanders Vaccine is to build partnerships and ensure coordination between relevant actors and sectors involved in innovation and supply of vaccines and immunotherapeutics. An innovation-friendly R&D environment is absolutely crucial to drive the development of vaccines and immunotherapeutics, widely recognized as essential tools in the maintenance of public and animal health.

The goal of Flanders Vaccine is to build on Belgium's strengths in human and animal R&D to stimulate the development of vaccines and immunotherapeutics, with an emphasis on the One Health concept.

By organizing cross-fertilization between academic centers and bridging the gap between academic research, sme's and industry, Flanders Vaccine aims to be an important facilitator for enabling ground-breaking research. Sharing of knowledge and expertise will generate many opportunities in the discovery-development-supply spectrum that give rise to highly valued interactions between multiple disciplines. Permanent consultation between partners from the academic field, industry, public/government agencies and patients will lead to safe and effective innovations that will improve healthcare and enable the interception of many diseases.

www.flandersvaccine.be

Founding partners



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PROGRAMME

09:45 Welcome

Morning Session: The importance of (innovative) animal models for vaccine development

Moderator Prof. Niels Hellings, UHasselt

10:00 **In search for models predicting clinical success; lessons learned from COVID-19**

Dr. Kai Dallmeier, Group Leader Molecular Vaccinology and Vaccine Discovery, KU Leuven, Belgium

10:30 **Modelling human cellular immune responses in humanized mice**

Prof. Dr. Christian Münz, Viral Immunobiology, Director of the Institute of Experimental Immunology, University of Zurich, Switzerland

11:00 Coffee break

11:30 **Pitch session**

12:30 Lunch & networking break

**Afternoon Session: Non-animal alternatives
for vaccine development**

Moderator: Prof. Jo Van Genderachter, VUB/VIB

14:00 **Resolving immunogenic exposures from the gut microbiome in human health and disease-Implications for vaccine development**
Prof. Paul Wilmes, Professor Systems Ecology, Luxembourg Centre for Systems Biomedicine, University of Luxembourg

14:30 **Update on EPAA projects on vaccines**
Dr. Marie-Emmanuelle Behr-Gross, Scientific Programme Manager, European Directorate for the Quality of Medicines and HealthCare (EDQM), Council of Europe

15:00 **Challenging Animal Models with Models of Challenges: RSV Finds Pharmacometrics for Leveraging Literature**
Dr. Jeffrey Sachs, Distinguished Scientist, PPDM-Quantitative Pharmacology and Pharmacometrics, MSD, US

15:30 Coffee break

16:00 **Panel debate "Successes & challenges in moving forward and beyond animal models in vaccine R&D"**
With Dr. Eddy Rommel, Rommel Consulting Partners SRL, Dr. Dirk Jochmans, KU Leuven and Prof. Dr. Joeri Aerts, VUB

16:45 **CLOSING KEYNOTE: Advancing translational research using porcine cancer models: current progress and future applications**
Dr. Kyle Schachtschneider, Research Assistant Professor, University of Illinois, Chicago, US

17:30 Pitch Award & Closing word

17:45 Networking reception

EDITORIAL



Dear Colleagues,

During this 6th edition of Immunity for Health we focus on “Animal models and alternatives for the development of vaccines”.

As illustrated in our first webinar on Science based solutions to control the COVID-19 crisis (June 2020) the selection of the right animal model is critical during non-clinical vaccine development. A one health approach and proper analysis of host-pathogen-microbiome interactions, pathology and immune reaction in the animal model is important to maximize the success of the translation in expensive trials in the clinical phase.

Due to the complexity of the immune response, animal models today are still essential for the development and non-clinical demonstration of efficacy and safety of innovative vaccines. In recent years however substantial progress has been made in reducing and replacing the number of animals used for said non-clinical vaccine research.

We are very pleased and honored that we can welcome renowned speakers who will share their latest scientific data on innovative alternatives such as in-vitro and in-silico models for future vaccine development and quality control.

The challenges in moving forward and beyond animal models, such as ethical and regulatory issues, will be discussed in a vibrant panel debate.

On behalf of the Board of Directors and the entire team of Flanders Vaccine, I wish you an inspiring conference.

Best Regards,

Sven Arnouts

Chairman Board of Directors, Flanders Vaccine

KEYNOTE



Kyle Schachtschneider

Research Assistant Professor at the Department of Radiology, University of Illinois, Chicago, US

Dr. Kyle Schachtschneider, Ph.D. is a Research Assistant Professor in the Department of Radiology at the University of Illinois at Chicago. He also holds appointments in the Department of Biochemistry and Molecular Genetics and the National Center for Supercomputing Applications.

His primary research goal is to improve treatment outcomes for cancer patients through the utilization of cutting edge porcine biomedical research platforms. To accomplish this, Dr. Schachtschneider leverages his background in bioinformatics, epigenomics, molecular biology, and the use of pigs in translational biomedical research. Dr. Schachtschneider graduated with a Bachelor's degree in Animal Sciences from the University of Illinois at Urbana-Champaign in 2008 and received his Ph.D. in Animal Sciences from the same institution in 2013 as part of the Comparative Genomics Lab headed by Dr. Schook. His work on porcine biomedical models continued as a Postdoctoral Research Associate at the world-renowned Wageningen University bioinformatics group in the Netherlands where he performed next-generation sequencing analysis to investigate genetic and epigenetic variation underlying disease in porcine biomedical models.

Following his time overseas he joined the Department of Radiology at the University of Illinois at Chicago to focus his research efforts towards translation into clinical practice. During his time at UIC, he has focused his efforts on development of Oncopig hepatocellular carcinoma and lung adenocarcinoma models, including utilization of these models for testing of novel treatment strategies to improve translation into clinical practice.

LECTURES



Marie-Emmanuelle Behr-Gross

Scientific Programme Manager, European Directorate for the Quality of Medicines and HealthCare (EDQM), Council of Europe

Dr. Marie-Emmanuelle Behr-Gross has graduated in Pharmacy at the University of Strasbourg. After a Pharm D and a spell in pharmaceutical practice, she has been teaching sciences and has undertaken fundamental research projects in biology.

After several years spent at the Regional Blood Center of Strasbourg (EFS Alsace), she earned a PhD in pharmacology and became a lecturer at the Faculty of Pharmacy of the University of Strasbourg. After an experience in development and control of Health products in the private sector, she joined the European Directorate for the Quality of Medicines and Healthcare (EDQM, Council of Europe) in 1997. At the EDQM she has been involved in the Biological standardisation programme, an applied research programme co-sponsored by the European Union and the Council of Europe for the establishment of reference preparations and methods for the quality control of biomedicines. From 2007-2010 she was the scientific secretary of the Transplantation steering committee and from 2007-2012 she was also the scientific secretary of the Blood transfusion steering committee of the Council of Europe. Since 2013, Dr. Marie-Emmanuelle Behr-Gross has joined the Biological Standardisation Programme.

She is experienced in the management of large international collaborative research projects, in coordinating policy advice (drafting of non-mandatory legal instruments) and publications activities (e.g. Council of Europe blood guide), as well as in the performance of enquiries, the organisation of specialised symposia and the management of ad hoc experts working on various topics.



Christian Münz

Professor Viral Immunobiology, Director of the Institute of Experimental Immunology, University of Zurich, Switzerland

Christian Münz has been trained in immunology at the German Cancer Research Institute in Heidelberg, Germany, the University of Tübingen, Germany, and the Rockefeller University in New York, USA.

He became Assistant Professor and Head of Laboratory at the Rockefeller University in 2003. In 2008 he was recruited as Associate Professor and Co-Director of the Institute of Experimental Immunology to the University of Zürich, Switzerland, and became Full Professor in 2015. Since 2010 he is also Visiting Professor at the Imperial College in London, UK.

In 2006 he received the Burroughs Wellcome Fund Investigators in Pathogenesis of Infectious Disease Award for his studies on antigen processing via macroautophagy, and in 2012 the Sobek Award for his studies on the association of Epstein Barr virus (EBV) infection with multiple sclerosis (MS). He is an expert in EBV specific immune control and humanized mice as preclinical models for human oncogenic gamma-herpesvirus infections, and has published more than 270 peer reviewed papers and review articles on these topics.



LECTURES



Paul Wilmes

Professor of Systems Ecology, Luxembourg Centre for Systems Biomedicine (LCSB), University of Luxembourg and Head of the Eco-Systems Biology research group

Prof. Wilmes obtained his PhD in 2006 from the School of Environmental Sciences at the University of East Anglia in Norwich (UK), a part of his doctoral research having been conducted at the Max Planck Institute for Marine Microbiology in Bremen (Germany). After postdoctoral research at the University of California, Berkeley (USA), he returned to his native Luxembourg in 2010 through an ATTRACT Fellowship of the Luxembourg National Research Fund (FNR). He initially established his research group at the Centre de Recherche Public – Gabriel Lippmann but later joined the LCSB where he was promoted to Associate Professor in 2015. In 2019, Paul Wilmes was awarded a Consolidator Grant from the European Research Council (ERC). He was promoted to Full Professor in 2020.

Paul's main primary research focus is on using Systems Biology approaches to identify key functionalities of microbial communities including human associated microbiota. His group has pioneered appropriate methodologies for carrying out systematic molecular measurements of microbial consortia over space and time. This allows for example to define lifestyle strategies of distinct populations and link these to genetic and functional traits. The same approaches allow the study of microbiome-host molecular interactions. In this context, his group has pioneered the development of a microfluidics-based models of the human-microbial gastrointestinal interface.

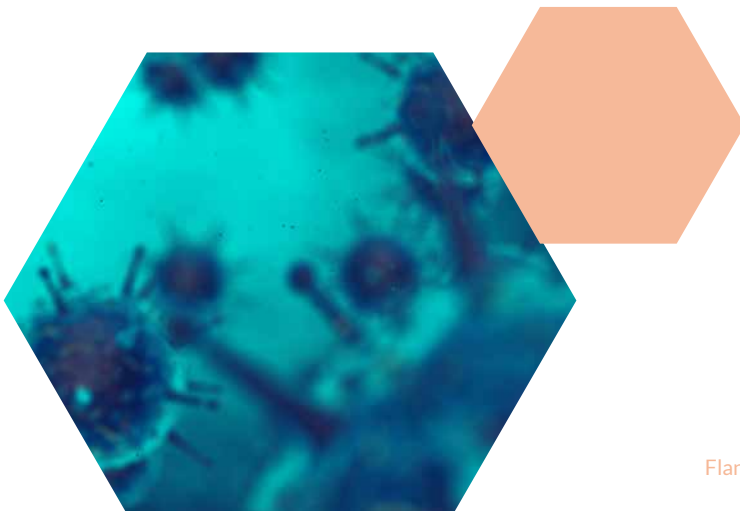


Kai Dallmeier

Group Leader Molecular Vaccinology & Vaccine Discovery, KU Leuven, Rega Institute, Belgium

Kai Dallmeier, PhD, studied Microbiology, Biochemistry and Biophysics at the University of Bremen, Germany and obtained a PhD from the University of Freiburg, Germany, for his studies on the host tropism of hepatitis B viruses in animal models.

In a multidisciplinary approach and using the live-attenuated yellow fever vaccine as platform, Kai and his team develop vaccines for emerging infections (such as Zika, Ebola and COVID-19) as well as therapeutic vaccines (for instance for chronic hepatitis B). Thermostable and easy to manufacture plasmid-launched versions thereof aim to tackle vaccine shortage and unmet public health needs faced particularly by people living in LMIC.



LECTURES



Jeffrey R Sachs

Distinguished Scientist, PPDM-Quantitative Pharmacology and Pharmacometrics, MSD, US

Jeffrey R. Sachs, PhD is a distinguished scientist in the PPDM-QP2* Department in Merck Research Laboratories, where he is responsible for modeling and simulation from early discovery through late stage clinical for the Vaccines therapeutic area. He has over 70 publications. (*Pharmacokinetics, Pharmacodynamics, and Drug Metabolism – Quantitative Pharmacology and Pharmacometrics)

Dr. Sachs received his BS and MS in Applied Math from Brown University and his PhD in Math at MIT where he worked with Alan Grodzinsky on the electromechanochemistry of articular cartilage in order to help design minimally-invasive arthroscopic diagnostic devices. After several academic and government postdoctoral appointments in Applied Physics (Univ. Tokyo), Biomedical Engineering (Northwestern Univ.), and Biotechnology (N.I.S.T.), he developed two successful biotechnology consulting businesses. He came to Merck in 1999 and worked on gene expression analysis, on data mining and SAR integration platforms, and as lead inventor of Merck's proteomics and metabolomics technology platforms. He then led the Therapeutic area aligned modeling and simulation group, and lead the design, implementation, and global deployment of a web-based tool providing a user-friendly, non-technical, modeling interface for internal and external decision makers. That tool is being used across many programs and therapeutic areas and helped MSD gain recommendations for compounds in over 40 countries. He previously also led the department's efforts in Infectious Diseases, in Oncology, and in digital health/adherence strategy. He is currently the QP2 Therapeutic Area Lead for vaccines, and the QP2 Program Lead for the COVID and Dengue vaccine programs.

PITCH PRESENTERS



An innovative organoid based oncology platform for humanized vaccine research

Authors: Kim Frederix, Sarah Aerts, Wim Tiest, Marième Ndjinn

Presenter: Kim Frederix, Director Innovation, InnoSer Belgium NV


Over the last years, InnoSer has put tremendous effort towards building a proprietary line of organoids and xenografts derived from the same clinical tumor resection specimen or biopsy, and this for several cancer subtypes such as lung, pancreas, esophageal or stomach cancer.

With these samples a pipeline of in vitro and in vivo models is being built suitable for any type of treatment screening in oncology.

Because of the importance of the immune component in many of the more recently developed therapies, it is important to be able to use the models in an immune competent background.

Due to the human nature of our collected samples the only possible solution was a humanized mouse model, which we are developing in alliance with Genoway and the BRGSF-His mouse they developed.

This mouse has a CD34 reconstituted immune system where all the hematopoietic subsets are represented and functional, B and T cells, NK, DC and monocytes/macrophages. Taken together with our very well characterized tumor models (Mutations, RNAseq, IHC, patient history) can offer a platform to use in vaccine research in an innovative and even personalised medicine setting.



Immunopeptidomics as a tool to identify relevant antigens for vaccine development

Authors: Elise Pepermans, Daniel Flender, Kurt Boonen, Geert Baggerman

Presenter: Geert Baggerman, Professor, Centre for Proteomics; VITO, Universiteit Antwerpen, Belgium

Antigens are presented by the major histocompatibility complex (MHC) on the surface of cells to T-cells where they mediate (antigen specific) immune responses. The identification of antigens that will lead to an immune response is of major importance for the development of vaccines for viral and bacterial infections and for certain types of cancer. As the majority of the immunopeptides (the antigens presented by the MHC complexes) are self-peptides (i.e. coming from non-aberrant endogenous proteins) the identification of aberrant immunopeptides (tumor specific antigens and tumor associated antigens (in the case of cancer), and non-self peptides (in the case of bacterial or viral infection)) by mass spectrometry can be very difficult. However, the recent improvements in mass-spectrometers combined with advances in bio-informatic analysis now allow for an improved analysis of antigen presentation from lower amounts of sample allowing better identification of the aberrant immunopeptides.

At the Centre for Proteomics, we recently developed

1. a workflow combining multiple experimental approaches allowing the isolation and identification of immunopeptides and their analysis using state-of-the-art trapped ion mobility mass spectrometry (which amplifies the number of immunopeptides identified) from mouse tissue.
2. an optimized combination of bio-informatic tools which drastically improves the identification of the immunopeptides from the obtained MS data.

Besides the isolation and identification of human immunopeptides we recently also developed protocols for the isolation and identification of immunopeptides in mice/murine samples.

AI-based decoding of the T-cell repertoire

Authors: Sander Wuyts, Pieter Meysman, Tom Bosschaerts, Benson Ogunjimi, Kris Laukens

Presenter: Sander Wuyts, CEO startup ImmuneWatch, Belgium

The T-cell receptor repertoire holds the key to understanding how our immune system responds to infections, tumours, immune therapies or vaccines. We therefore believe that sequencing and analysing the human T-cell repertoire allows for faster development of improved vaccines and immune therapies. However, currently T-cell receptor repertoire analysis is complex and hard to interpret. Innovation in bio-informatic methodologies is necessary to transform this data source into clinically relevant knowledge.

We have developed an artificial intelligence-based decision support technology transforms T-cell sequencing data into actionable insights. Our comprehensive ImmuneMap reveals past exposures, elucidates current responses and predicts future protection of an individual to an ever-growing collection of antigens.

In vitro dendritic cell-based assays for vaccine immunogenicity assessments

Authors: Jana Schockaert, Sofie Pattijn, Chloé Ackaert, Aurélie Mazy, Ellen Boelen

Presenter: Chloé Ackaert, senior scientist, ImmunXperts, a Nexelis Company, Belgium

Early assessment of the immunogenicity of vaccine candidates is an important asset to select the most potent antigens and adjuvants, and to ensure the vaccine candidate induces the desired immunological response. In vitro assays with primary human immune cells can be used to assess the innate and adaptive immune response and to pre-screen vaccine candidates. Dendritic cells are the main orchestrators of the immune system and the link between innate and adaptive responses. Their activation by vaccines is an essential step in vaccine-induced immune responses. Monocyte-derived dendritic cells are loaded or transfected with vaccine candidates and evaluation of activation and maturation factors can be evaluated via flow cytometry while the cytokine profile can be analysed using Luminex.

Upon co-incubation with autologous T-cells, the potential to induce a vaccine specific immune response is evaluated via multicolor Fluorospot or intracellular cytokine evaluation via flow cytometry.

An important factor for reliable and reproducible results is the viability and quality of the primary immune cells and therefore, standardized procedures for collection, cryopreservation and handling of these cells need to be established. In vitro DC and DC:T cell assays can be used for early assessment of the potency and functionality of both infectious and personalized vaccine candidates.

Establishment of outbred pre-exposed pigs as an animal model for *Chlamydia trachomatis* vaccine development

Authors: Amanda Amaral, Volker Gerdts, François Meurens, Toni Darville and Tobias Käser

Presenter (online): Tobias Käser, Assistant Professor at the Department of Population Health and Pathobiology, College of Veterinary Medicine, North Carolina State University, US

Chlamydia trachomatis (Ct) is the most frequent sexually transmitted bacterial infection worldwide. Infections in women can lead to infertility, chronic pelvic pain and ectopic pregnancy. Nevertheless, a vaccine is currently not available partly due to the lack of appropriate animal models. The pig has been proven to be a valuable animal model for vaccine development: i) It is receptive to Ct; ii) It is the natural host to a close relative of Ct – *Chlamydia suis* (Cs); and iii) It accurately resembles Ct infection and immunity in humans. We established Cs pre-exposed pigs as a model for Ct vaccine development: this model has the unique ability to mimic the main population used during phase III clinical trials for Ct vaccine development – genetically diverse, and mostly Ct pre-exposed humans. In the first animal trial, we studied infection and the resulting immune response of Cs and Ct infections in pigs: most importantly, we demonstrated that Cs pre-exposure induced an immune response that is cross-reactive with Ct. In a second animal trial, we verified in a proof-of-principle Cs vaccination study that this model can be used to assess both, vaccine immunogenicity and efficacy. Vaccination with a TriAdj-adjuvanted and UV-inactivated Cs vaccine induced CD4 T-cell differentiation into IFN- γ + tissue-homing effector memory T cells; on top, it significantly reduced the genital Cs burden. Future studies will use this biologically highly relevant animal model for Ct vaccine development.

PANEL



Eddy Rommel

DVM, MSc and Graduated in Laboratory Animal Sciences, Eddy has 30+ years of experience in animal experimentation in academic and pharma / biotech contexts.

He worked for 14 years at GSK Biologicals as Associate Director In-vivo quality control, regulatory affairs, responsible of animal facilities and chairman of the Ethical Committee.

Since he founded Rommel Consulting Partners 20 years ago, Eddy provides consultancy services in Laboratory Animal Sciences, preclinical development and regulatory, with a focus on Cell and Gene Therapies, prophylactic and therapeutic vaccines.



Dirk Jochmans

Dirk Jochmans is a senior research manager at the Rega Institute at the University of Leuven (KU Leuven, Johan Neyts' lab) since 2010. He is currently involved in different European programs focusing on novel antiviral therapies for neglected and emerging viral infections.

Before 2010 he worked for more than 10 years in the pharmaceutical industry where he coordinated early discovery programs of novel antivirals against HIV. He is team member of the project OrganoVIR, which aims to study viruses with organoids in order to prevent future infections and to test vaccines. In addition, organoid technology can also replace animal models and thus reduce animal use in virology. Within the project, Dirk contributes to the research on human airway organoids.

PANEL



Joeri Aerts

During his graduate studies, Professor Joeri Aerts became intrigued by the complexity and intertwining of different components of the immune system. After his PhD, he became fascinated by how the immune system fights cancer and decided to take up a postdoctoral position at the NIH, where he was initiated in tumor immunology under the guidance of Dr. Suzanne Topalian. After that, he spent a short but productive period at the Barts Cancer Institute in London, studying oncolytic adenoviruses under the guidance of prof. Iain McNeish.

In 2004, he returned to Belgium and started first as a postdoc, then as an assistant professor at the LMCT (VUB), led by prof. Kris Thielemans, where he continued working on tumor immunology and immunotherapy.

Since 2015, he runs his own group (NAVI) and tries to bring together many of the topics he studied before, with as central themes tumor immunology, with a focus on enhancing the immunogenicity of oncolytic viruses, HIV immunology, studying the role of NK cells in the control of the viral reservoir and the development of novel RNA based therapeutic vaccines. Since it became clear that a dysregulation of the immune system lies at the root of the recent COVID-19 outbreak, his lab is now also studying various immune aspects in COVID-19 patients.

Currently, seven PhD students are working on these topics, mostly in national and international collaborations. Joeri Aerts also teaches various courses, where he tries to convince young students of the beauty of science in general and immunology in particular.

SCIENTIFIC COMMITTEE



We would like to thank the Immunity for Health 2021 Scientific Committee for their appreciated contribution!

Fran Van Heuverswyn

Project Manager, Flanders Vaccine

Sven Arnouts

Business Development Manager, PROVAXS - Ghent University

Niels Hellings

Professor Immunology, Hasselt University & Director BioMed

Katrien Lorré

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Professor Immunology, Vrije universiteit Brussel, Group Leader at VIB-VUB

Johan Neyts

Professor Virology, University of Leuven, Belgium



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Bhupal Senior Scientist, UK

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- Regulatory Affairs training and intelligence services.
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- We have supported big pharma and SME's with innovative vaccines/immunotherapeutics, including novel production platforms and for global public health needs.
- We are well linked with the Belgian Agency (FAMPH), EMA and EU Agencies with spearheads in these areas.
- We are well linked with other strategic partners active in these areas.

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