



FIGONDMD

1-2 October 2018, De ReeHorst - Ede

PROGRAM

Congress on Innovative
Drug Research
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MEDICINES

FIGON Dutch Medicines Days 2018

Dear participants in the 20th edition of the Dutch Medicines Days,

At FIGON (the integrative platform for innovative drug research in the Netherlands) we consider it very important that good connections exist between the different partners (Industry, Academia and Government) involved in drug research. Strong interactions between these stakeholders will increase the societal impact of Dutch drug research. The FIGON-Dutch Medicines Days is the conference where everyone that is involved in drug research in the Netherlands present their findings, share new scientific content and strengthen their networks.

Well-known ingredients of the Dutch Medicines Days are the PhD Student Competition, the Ariëns lecture and the Prix Galien (Research Award and Pharmaceutical Award) ceremony and mini-symposium. In the coming two days, these established elements will be combined with different plenary and parallel lectures in which (international) key opinion leaders present and discuss the latest developments and where young investigators get the opportunity to present their research in poster- and oral presentation sessions.

All research schools involved in drug research in the Netherlands send the PhD student with the best abstract presentation in an internal PhD competition to the DMD PhD Student Competition. Winning the PhD Student Competition is therefore an important achievement.

Next to the partners that have been visiting the DMD for many years, last year we involved Biotech Companies in the program and we are now welcoming new Start-up companies. There will be plentiful network time during the 2-days congress, providing extensive possibilities to establish contacts with potential clients, partners and maybe new employees or employers. To facilitate the latter, students, PhD's, post-docs and academic staff are invited to meet and greet representatives of pharmaceutical companies to learn about career opportunities in industry involving regulatory affairs, medical Information/affairs, clinical operations, liaison, and research.

Of course I would like to thank the organizing committee of the FIGON Dutch Medicines Days: Gerard Rongen, Linette Willemsen, Ingrid Dijkgraaf, Just Weemers, Marc Ditmarsch and Mathijs de Kleer and all representatives of FIGON-partners in the scientific committee for their enthusiasm and hard work to put together this amazing program.

I wish you two very exciting days in the Reehorst, and I hope you will leave the DMD with lots of new research ideas, and lots of business cards of new people to collaborate with,

Enjoy!

Prof. Dr. Anke-Hilse Maitland-van der Zee
President FIGON



Organizing & Scientific Committee

Organizing Committee

Gerard Rongen
Linette Willemsen
Ingrid Dijkgraaf
Just Weemers
Marc Ditmarsch
Mathijs de Kleer

Radboud UMC Nijmegen
Utrecht University
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	RSNN	Regulatory Science Network Netherlands
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	Vereniging Innovatieve Geneesmiddelen	www.vereniging innovatievegeneesmiddelen.nl
	ZonMW	www.zonmw.nl

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General information

Dutch Medicines Days 2018

October 1st - 2nd
www.figondmd.nl

Venue

Conference center the ReeHorst
 Bennekomseweg 24
 6717 LM Ede
 T: 0031 (0) 318 750 300
 E: info@reehorst.nl

The official language is English.

Congress organizer

TCM Congress Management BV
 De Corridor 14K
 3621 ZB Breukelen
 T: 0031 (0) 346 251 566

☒ TCM
☒ CONGRESS
☒ MANAGEMENT

Industry Area

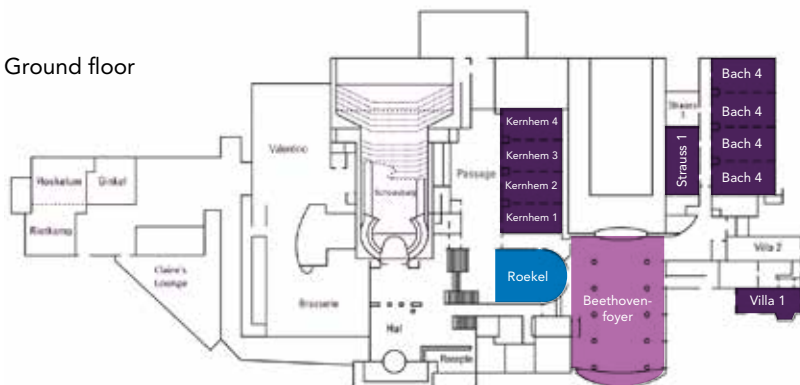
The Industry area is at the heart of the congress. Here visitors and business partners can meet in an informal and interactive setting. At the Industry area, commercial and scientific partners will be able to inform interested parties about their science, business, products and careers.

Name badges

All delegates will receive a namebadge upon registration at the registration desk. All participants are kindly requested to wear their badges throughout the congress. Only participants wearing their name badge will be admitted to the sessions and social activities.

Floor plans conference centre the ReeHorst

Ground floor



Basement



CLINICAL AND TRANSLATIONAL PHARMACOLOGY

Room: BACH 1-2
Time: 09:00 - 11:00
Chair: Cornelis Kramers
Organizing FIGON partner: Dutch Society for Clinical Pharmacology and Biopharmacy (NVKFB)

The theme of this year is "Predictive value of preclinical research for clinical pharmacology". We start with an stimulating keynote lecture by Prof. Dr. Jan Danser showing the relevance of preclinical work and the translation to the clinical setting by an interesting lecture on preeclampsia and VEGF inhibitors. Since the severe side effects of VEGF inhibitors used in oncology such as hypertension and nephropathy resemble the severe complication of pregnancy preeclampsia, preclinical work using VEGF inhibitors can give important information about treatment options for preeclampsia and vice versa. This is an illustrative example of combining basic pharmacology with clinical pharmacology to optimize understanding and treatment options. This lecture is followed by four oral presentations of original research from selected abstracts showing the full scope of clinical pharmacological research performed in the Netherlands. So in this session you will find pharmacokinetic studies, translational pharmacology, personalized pharmacotherapy and pharmacoepidemiology. In conclusion, a very attractive session not to be missed by anyone interested in translational and clinical pharmacology.

Invited lecture:

9:00 – 09:40 Predictive value of preclinical research: VEGF inhibitor-induced toxicity and preeclampsia
A.H. (Jan) Danser, Erasmus University Medical Center, Rotterdam

Selected abstracts:

09:40 – 10:00 Development of a pediatric brain PBPK model in children with and without meningitis.
L.F.M. (Laurens) Verscheijden, Radboud Institute for Molecular Life Sciences, Nijmegen

10:00 – 10:20 High inpatient variability in tacrolimus exposure is not associated with immune-mediated graft injury after liver transplantation
M.A.A. (Marlotte) van der Veer, Erasmus University Medical Center, Rotterdam.

10:20 – 10:40 The effect of rapid infusion of cisplatin on nephrotoxicity in patients with lung carcinoma
E.S. (Eveline) Mense, OLVG Hospital, Amsterdam

10:40 – 11:00 Benefit of statins after a first myocardial infarction in the oldest old.
Acohort study using general practitioner data from the CPRD.
G.J. (Geert) Lefeber, UMC Utrecht

Indicated speaker time includes 5 minutes for discussion

ONCOLOGY, INNOVATION AND DRUG PRICING

Room: BACH 3-4
Time: 09:00 - 11:00
Chair: Hans Büller
Organizing FIGON partners: L.P.S.V. „Aesculapius” & K.N.P.S.V.

MONDAY

Just criticizing the classic pharma makes no sense. Come up with something better. Our chair, Hans Büller, is the founder of the organization 'Fair medicine'. Fair medicine tries to ensure access to safe, effective and affordable medicines for everyone. Two speakers are invited, Jeroen van Smeden, who will explain the developing costs in drug research and the solutions and ideas used at the Centre for Human Drug Research (CHDR) to limit those costs. Furthermore Simon van der Schans of Fair medicine will talk about his research on the pricing of medicine. Drug discussion is mainly about the pricing of medicines, a good understanding of this is crucial to bring about a positive change.

09:00 – 09:15 Introduction by prof. Hans Büller – Fair Medicine

Invited lectures:

09:15 – 09:50 Developing costs in drug research
Dr. Jeroen van Smeden – Centre for Human Drug Research (CHDR)
Leiden

09:50 – 10:25 Pricing of medicine
Simon van der Schans – Fair Medicine

Selected abstract:

10:25 – 10:50 Stakeholder Perspectives on Implementing Personalized Medicine
in Diabetic Kidney Disease
Michelle Pena – University Medical Center Groningen (UMCG)

10:50 – 11:00 Round up by prof. H. Büller, room for questions and discussion

Indicated speaker time includes 5 to 10 minutes for discussion



1+1=3: INTERMUTUAL BENEFIT TO TREAT CARDIOVASCULAR AND RENAL DISEASES

Room: CERISE
Time: Monday 09:00 - 11:00
Chairs: Martina Schmidt & Joost Rutten
Organizing FIGON partners: Dutch Society for Clinical Pharmacology & Biopharmacy (NVKFB) and the Dutch Pharmacological Society (NVF)

Manuela Zaccolo graduated in medicine at the University of Torino, Italy. She is Professor of Cell Biology in the Department of Physiology, Anatomy and Genetics and Director of the Burdon Sanderson Cardiac Science Centre at the University of Oxford, UK. She is also a Tutor and Fellow Balliol College, Oxford. Her research focuses on how cardiac myocytes sense external stimuli and how these are processed to produce a functional outcome. She is interested in the architectural and regulatory principles by which intracellular signalling networks achieve the plasticity and context-sensitivity necessary for the myocyte to function. In particular, her work has focused on cyclic nucleotide signalling and on the role of local regulation by phosphodiesterases. Central to her approach is the use of FRET-based reporters and real-time imaging to dissect the topography and function of subcellular cyclic nucleotide nanodomains. Her ultimate goal is to understand how alteration of compartmentalised cyclic nucleotide networks leads to cardiac disease and to apply this knowledge to the development of novel therapeutic strategies.

Invited lecture:

09:00 – 09:30 Cyclic AMP nanodomains: potential implications for novel cardiac therapeutics
Prof. Dr. Manuela Zaccolo – University of Oxford, UK

Selected abstracts:

09:30 – 9:50 Comparison of three different platelet function tests in patients on P2Y12 inhibitors in correlation to genetic background.
Renske Olie – University Medical Centre Maastricht

09:50 – 10:05 Prediction of the effect of dapagliflozin on renal and heart failure outcomes based on short-term changes in multiple risk markers
Nienke Idzerda - University Medical Centre Groningen

10:05 – 10:20 Urate transporter mRNA expression profile in human endothelial cells. Comparison between umbilical vein and aorta
Larissa Govers - Radboudumc

- 10:20 – 10:35 Submicroscopic cAMP/PKA compartmentalization: Ion flux at the cardiomyocyte plasmalemma
Nushunge Musheshe - University Groningen
- 10:35 – 10:55 3D NephroScreen: high throughput drug-induced nephrotoxicity screening on a proximal tubule-on-a-chip model
Christian Ramakers - Mimetas Leiden

Indicated speaker time includes 5 minutes for discussion



REGULATORY CHALLENGES FOR THE NEXT WAVE OF CANCER THERAPIES

Room: KERNHEM 1-2
Time: 09:00 - 11:00
Chair: Sjaak Bot (Janssen)
Organizing FIGON partner: Regulatory Science Network Netherlands (RSNN)

MONDAY

A wave of innovative oncology treatments is progressing from bench to clinic. This includes treatment strategies such as chimeric T cell receptors (CAR-T) and other approaches that are categorized as Advanced Therapy Medicinal Products by the EMA. These products have the potential to transform the future of oncological treatment, but require innovative approaches concerning the risk-benefit assessment and subsequent market access. In this session we will discuss questions such as: Is the current regulatory landscape ready to facilitate registration of these innovative therapies to patients at the earliest appropriate time? Can we learn from the hurdles and barriers in the current ATMP regulation to prepare ourselves for new cancer therapies such as CAR-T?

09:00 - 09:10 Introduction

Invited lectures:

09:10 - 09:35 Regulatory considerations for ATMP based cancer therapies
Dr. Marcel Hoefnagel – Medicines Evaluation Board (CBG-MEB)

09:35 - 10:00 Planning for successful and efficient ATMP development
Dr. Harm Hermesen – Xendo

10:00 - 10:25 Access to innovative cancer therapies: the patient view
Dr. Pauline Evers – nfk

Selected abstracts:

10:25 - 10:40 Challenges in Commercial Advanced Therapy Development in Europe
Renske ten Ham - Utrecht University

10:40 - 11:00 Panel discussion

Indicated speaker time includes 5 minutes for discussion

MEDICINAL CHEMISTRY

Room: KERNHEM 3-4
Time: 09:00 - 11:00
Chair: Ingrid Dijkgraaf
Organizing FIGON partner: KNCV section Pharmacochimistry

The program of this session will be interdisciplinary and address interesting research topics, ranging from in silico design and chemical synthesis of bioactive molecules to set up of in vitro assays. Therefore, this session is accessible to a wide public. Between lectures, there will be time for questions and discussion to make this an inspiring meeting for both presenters and audience. Presentations will be given by researchers from academia and industry (Janssen Pharmaceutica N.V.). The PhD student who gives the best presentation (morning and afternoon session) will have the chance to represent the Dutch Medicinal Chemistry community at the European Federation for Medicinal Chemistry (EFMC) Young Medicinal Chemist Symposium.

Selected abstracts:

- 09:00 – 09:20 Design and synthesis of a multivalent catch-and-release enzyme inhibitor to measure coagulation factor XIa in blood circulation Stan van der Beelen – Maastricht University
- 09:20 – 09:40 Functionalization of tumour-targeting antibodies via enzymatic oxidation of tyrosine to 1,2-quinones Jorick Bruins – Wageningen University
- 09:40 – 10:00 Characterization of novel ENT1 inhibitors; Structure-affinity and structure-kinetic relationships Anna Vlachodimou – Leiden University
- 10:00 – 10:20 Drug discovery at the speed of sound Shabnam Shaabani – University of Groningen

Invited lecture:

- 10:20 – 11:00 Biosignature-Based Drug Design: A New Drug Design Paradigm Dr. Jörg Wegner – Janssen Pharmaceutica N.V., Beerse

Indicated speaker time includes 5 minutes for discussion

MONDAY



OFFICIAL OPENING BY FIGON PRESIDENT: PROF. DR. A.H. MAITLAND-VAN DER ZEE

Room: THEATRE AZURE
Time: 11:30 - 11:40
Speaker: Prof. Dr. A.H. Maitland-van der Zee, FIGON President

ECOLOGICAL IMPACT OF DRUG DEVELOPMENT AND APPLICATION

Room: THEATRE AZURE
Time: 11:40 - 12:05
Speaker: Dr. Ir. N.W. (Nico) van den Brink, Associate professor, Department Toxicology, Wageningen University

TUMOR VACCINATION WITH (ANTIGENICALLY LOADED) DENDRITIC CELLS

Room: THEATRE AZURE
Time: 12:05 - 12:30
Speaker: Prof. Dr. J. (Jolanda) de vries, Professor Department of Tumor Immunology, Centre for Molecular Life Sciences, Radboudumc Nijmegen

Dendritic cell-based vaccination against cancer: From hypothesis to daily practice. Dendritic cells (DCs) were first discovered by Steinman and Cohn in 1973. DCs are the most potent antigen-presenting cells of the immune system. Under steady state conditions, immature DCs sample peripheral tissues in search for pathogens or tissue injury, but when encountering danger signals, they quickly differentiate into activated (mature) DCs and migrate to lymphoid organs to induce an adaptive immune response. In lymphoid tissues, mature DCs initiate immune responses by presenting captured antigens to naïve T cells, in the form of peptide-major histocompatibility complex (MHC) molecule complexes. These T cells will proliferate and differentiate into effector cells that are able to kill cells in an antigen-dependent manner. Vaccination with dendritic cells (DC) loaded with tumor peptides is feasible, safe, and

can induce tumor-specific immune responses in advanced cancer patients. To date, Dendritic Cell (DC)-based immunotherapy is explored worldwide in clinical vaccination trials with cancer patients. So far, predominantly ex vivo-cultured monocyte- or CD34+ derived DCs have been used. Although during the past 15 years the concept of DC vaccination has been clearly proven and found safe, the number of patients that have long-term benefit is limited. Instead of monocyte derived DC, we recently performed studies with two major types of naturally occurring DCs: myeloid DCs and plasmacytoid DCs. These different natural DC subsets, expressing distinct TLRs, do not require extensive in vitro culture, and provide us with a novel toolbox to more precisely explore the therapeutic potential of natural DC in cancer immunotherapy. The first results indicate that these cells are extremely potent in initiating immune responses in cancer patients. Next steps include a phase III trial to ultimately prove clinical benefit, the use of neoantigens to improve vaccine efficacy, combination of DC vaccines with other types of immunotherapy, and development of tools to predict which patients will benefit most from dendritic cell vaccination.

DRUG, DRUG REDISCOVERY PROTOCOL STUDY – INSIGHTS THE ACADEMY

Room: THEATRE AZURE
Time: 12:30 - 13:00
Speaker: Prof. Dr. E. (Emile) Voest, MD
 Professor of Medical Oncology,
 UMC Utrecht and Medical
 Director, Dutch Cancer Institute

Emile Voest is professor of Medical Oncology and serves as Medical Director on the executive board of the Netherlands Cancer Institute in Amsterdam. He also serves as on the board of the Center for Personalized Cancer Treatment (a national personalized medicine program involving >30 hospitals) and as member of the executive board of ESMO (treasurer and chair of the audit committee), member of the supervisory board of the Hartwig Medical Foundation (national sequencing center) and as immediate past-chair of ASCO's Cancer Research Committee.

His research efforts focus on improving systemic treatment for patients with cancer. This includes the clinical development of targeted agents, discovery and validation of biomarkers with emphasis on genetics and tumor organoids, and identification of new targets of treatment to overcome chemo resistance.



MODERATED POSTER TOUR

Room:

BEETHOVEN FOYER

Time:

13:30 - 14:30

In advance to the FIGON Dutch Medicines Days, poster abstracts were selected by the Scientific Committee. The selected nominees are invited to present their poster during the moderated poster session at the Dutch Medicines Days 2018. There are 6 prizes available for the best research poster presentations. Only attendees who attend the moderated poster tour can qualify for these prizes. On Tuesday October 2nd, the winners will be announced during the afternoon prize ceremony.

Poster categories 2018:

1. Clinical (translational) pharmacology
2. Pharmacology: pre-clinical models
3. Regulatory challenges and Teaching (clinical) Pharmacology
4. Medicinal Chemistry
5. Receptor pharmacology and signal transduction / Drug formulation, delivery and targeting
6. Drug utilization, pharmacokinetics and drug safety

THE ARIËNS LECTURE 2018

Room:

THEATRE AZURE

Time:

17:00 - 18:00

Speaker:

Prof. John. D. Scott, University of Washington in Seattle

Exploring and exploiting the constraints of local cell signaling.

The board of the Dutch Pharmacological Society is honored to announce Prof. John D. Scott, University of Washington in Seattle as recipient of the 2018 Ariëns Award, an award in memory of Professor E.J. Ariëns (1918 – 2002), and given annually as a recognition of outstanding scientific achievements in pharmacology.

John Scott is head of the Division Pharmacology at the University of Washington School of Medicine, Seattle. He is also entitled as Edwin G. Krebs-Hilma Speights Professor. He received his B.Sc. (Hons) degree from Herriot-Watt University, Edinburgh, and his Ph.D. degree from the University of Aberdeen. He did postdoctoral research on protein kinase inhibitors in the laboratory of Edwin Krebs at the University of Washington. Edwin Krebs received the Nobel Prize for Physiology in Medicine in 1992.

John Scott joined the faculty of the University of California, Irvine before moving to the Vollum Institute at the Oregon Health & Sciences University, Portland.

John Scott is interested in the specificity of signal transduction events that are controlled by anchoring proteins, which facilitate rapid signal transduction by optimally positioning protein kinases and phosphatases in the vicinity of their activating signals and close to their substrates. His research has led to novel insights in the field of signaling in space and time. He made major contributions to the development of novel therapeutics to treat heart failure and diabetes. Currently he drives the field to concept of using the family of anchoring proteins to specifically target drug to subcellular locations to improve personalized medicine and drug targeting strategies. The field of protein-protein interactions is rapidly developing, getting thereby more and more into the focus of national and international meetings. Here it is worthwhile to mention the symposium organized on the Dutch Medicine Days 2017 in the framework of the Prix Galien 2017, "Peptides and proteins are key", and the CHAIN Meeting 2017, "Chemistry as Innovating Science". John spans the broad area of cell signaling, biochemistry, physiology and pharmacology.

Dr. Scott is a fellow of the Royal Society, London, and was recently elected a fellow of the Royal Society of Edinburgh, fellow of the American Association for the Advancement of Science, and fellow of the Norwegian Academy of Science and Letters. He received the Award in Pharmacology, American Society for Pharmacology and Experimental Therapeutics, the Ernst Oppenheimer Award, Endocrine Society, the William C. Rose Award, American Society for Biochemistry and Molecular Biology, the Medical Research Foundation of Oregon Discovery Award and the D. Harold Copp Award, University of British Columbia. His current h-index is about 102 (Google Scholar), and about 33109 citations.



CELL- AND GENE- THERAPIES FOR ONCOLOGY

Room: BACH 1-2
Time: 14:30 - 16:30
Chair: Massimiliano Caiazzo
Organizing FIGON partner: Utrecht Institute for
 Pharmaceutical
 Sciences (UIPS)

Session presentations will be given by researchers with both academic and medical background that will address recent advances in cancer treatment based on gene- and cell-therapies. Speakers will focus on cancer cell-based approaches focusing on immunotherapy with chimeric antigen receptor (CAR) T cells and on gene-therapy strategies employing oncolytic viruses. The seminars will also cover new developments in cancer diagnostics based on the analysis of tumor circulating cells and advanced therapeutic options focusing on cell-penetrating peptides and photoactivated chemotherapy.

Invited lectures:

- 14.30 – 15.00u Engineering immune cells – the next generation: from CAR T to TEGs
 Prof. Jurgen Kuball – University Medical Center Utrecht
- 15.00 – 15.30u Designed adenoviruses for effective oncolytic immunotherapy of cancer
 Prof. Victor van Beusechem – VU University Medical Center

Selected abstracts:

- 15.30 – 15.50u Circulating tumor cells and driver mutation analysis in cerebrospinal fluid in patients with epithelial tumors with suspected leptomeningeal metastasis
 Mark Van Bussel - NKI-AVL
- 15.50 – 16.10u Identification of the cell-penetrating peptide Pepfect14 for the efficient delivery of antisense oligonucleotides against AR pre-mRNA, for treatment of castration-resistant prostate cancer
 Omar Paulino Da Silva Filho- Radboudumc/RIMLS
- 16.10 – 16.30u Imaging of click-enabled ruthenium complexes for photoactivated chemotherapy
 Anja A Busemann - Leiden Institute of Chemistry

Indicated speaker time includes 5 minutes for discussion

PK AND ADR, FROM EARLY LIFE TO ELDERLY

Room: BACH 3-4
Time: 14:30 - 16:30
Chair: Jan Commandeur
Organizing FIGON partner: Dutch Society of Toxicology (NVT)

Drug development from phase I to IV usually takes place in adult patients. Sometimes drugs are especially designed for special patient groups and then research takes place in those groups. However, many drugs that are investigated in adults will be used at both ends of the human spectrum, from early neonates to the very old and in pregnant women. Usually pharmacokinetics and pharmacodynamics are highly different with sometimes unexpected side effects, and this leads to gaps in our knowledge how to use these drugs optimally and safely in these special groups. In this session examples of drug studies aiming at filling in these knowledge gaps will be presented.

Selected abstracts:

- 14:30 – 14:50 Preclinical requirements for anticancer drugs in the EU
Alex Zwiers – Zwiers Regulatory Consultancy
- 14:50 – 15:10 A human placental villous explant model to study the toxicity of drugs
Hedwig Hove - Radboud UMC
- 15:10 – 15:30 Adverse drug reactions in pediatric patients: are we doing the right thing?
Anne Dittrich - Amalia Childrens Hospital Radboudumc
- 15:30 – 15:50 Setting the stage for model-informed dosing of intravenous paracetamol in robust older people using population pharmacokinetic modeling
Paola Mian - ErasmusMC
- 15:50 – 16:10 Under-representation of elderly in clinical trials - an analysis of the approval documents in the FDA database
Rikje Ruiter - CHDR

Indicated speaker time includes 5 minutes for discussion

IMMUNO- AND NEUROPHARMACOLOGY

Room: CERISE
Time: 14:30 - 16:30.
Chairs: Linette Willemsen & Rahul Pandit
Organizing FIGON partners: Dutch Pharmacological Society & Rudolf Magnus Institute of Neuroscience

The complex interaction of genetic and environmental factors with the immune system is considered to be crucial for the development of immune and neurological disorders. Deciphering the pathogenesis of neuropsychiatric diseases remains a challenging task till date. This session opens with an invited lecture for an update on the role of the immune processes in the pathogenesis of Parkinson's disease. The session also discusses how dietary components modulating the innate immune system could be useful for treating neuropsychiatric disorders. Subsequent presentations of selected abstracts will shed light on the pathophysiology of immune diseases, neurological and degenerative brain disorders and will provide insight in ways for drug targeting.

Invited lecture:

- 14:30 – 15:10 The gut-immune-brain axis in Parkinson Disease - Food pharma interactions
Prof. dr. Aletta Kraneveld – Utrecht Institute for Pharmaceutical Science & Institute for Risk Assessment Sciences, Utrecht University

Selected abstracts:

- 15:10 – 15:30 Are some animal models more equal than others? A case study on Alzheimer's disease efficacy models
Desiree Veening-Griffioen, Utrecht University
- 15:30 – 15:50 High-throughput 3D brain model of iPSC-derived neurons and glia for prediction of neurotoxicity and safety pharmacology
Chiwan Chiang, Mimetas, Leiden
- 15:50 – 16:10 Development of novel HDAC inhibitors with improved selectivity to target inflammatory airway diseases
Fangyuan Cao, University of Groningen
- 16:10 – 16:30 Nanobody-Fc constructs targeting chemokine receptor CXCR4 inhibit signaling, HIV-entry and induce antibody effector functions
Vladimir Bobkov, VUMC Amsterdam

Indicated speaker time includes 5 minutes for discussion

EVIDENCE GENERATION FOR INNOVATIVE PRODUCTS IN ONCOLOGY

Room: KERNHEM 1-2
Time: 14:30 - 16:30
Chair: Marjon Pasmooij (CBG-MEB)
Organizing FIGON partner: Regulatory Science Network Netherlands (RSNN)

Given the high unmet medical need, the potential benefit to the patients and the limited therapeutic 'window of opportunity', there is an imperative to provide access to promising products to patients in an expedient manner. With a number of potential breakthrough therapies in the pipeline, there is a high need to discuss the type and the amount of evidence that can be collected during clinical development and the fact that a greater proportion of the evidence will need to be generated post-launch. In this session we want to focus on questions such as: What will future evidence generation strategies look like? What are the consequences of these developments for regulatory and HTA decision making? The speakers will focus on the types of evidence that different stakeholders need in their decision-making.

- 14:30 – 14:35 Introduction
- Invited lectures:**
- 14:35 – 15:00 Innovative evidence generation in oncology drug development - a system's approach
Paula van Hennik (CBG-MEB)
- 15:00 – 15:25 Evidence generation for innovative oncology products: an industry perspective
Alwin Otten (Janssen)
- 15:25 – 15:50 The EBMT Registry and CAR T Cells
Jürgen Kuball (UMC Utrecht)
- Selected abstracts:**
- 15:50 – 16:05 The value of real-world evidence in reimbursement decisions
Brenda Leeneman - Erasmus University Rotterdam
- 16:05 – 16:30 **Panel discussion**

Indicated speaker time includes 5 minutes for discussion

MONDAY



MEDICINAL CHEMISTRY

Room: KERNHEM 3-4
Time: 14:30 - 16:30
Chair: Ingrid Dijkgraaf
Organizing FIGON partner: KNCV section pharmacology

This afternoon session will be a continuation of the morning session Medicinal Chemistry. It addresses multidisciplinary research topics, ranging from design and synthesis of bioactive molecules to set up of in vitro assays. Researchers from academia will present their research. An interesting SME presentation in this afternoon session will be given by Merus N.V.. The PhD student who gives the best presentation (morning and afternoon session) will have the chance to represent the Dutch Medicinal Chemistry community at the European Federation for Medicinal Chemistry (EFMC) Young Medicinal Chemist Symposium.

Selected abstracts:

- 14:30 – 14:50u Exploring hit-identification strategies for energy-coupling factor transporters, a novel target for the development of antibiotics
Spyridon Bousis – University of Groningen
- 14:50 – 15:10u Disagregin: a platelet aggregation inhibitor from the tick *Ornithodoros moubata*
Danique van den Kerkhof – Maastricht University

Invited lecture:

- 15:10 – 15:50u Dock and Block: a novel approach to treat cancer with bispecific antibodies
Dr. Camilla de Nardis – Merus N.V., Utrecht

Selected abstracts:

- 15:50 – 16:10u Structural analysis of chemokine receptor-ligand interactions to support drug discovery
Marta Arimont – VU Amsterdam
- 16:10 – 16:30u Visualizing vitamin A metabolism
Sebastiaan Koenders – Leiden University

Indicated speaker time includes 5 minutes for discussion

Noties

MONDAY



INDUSTRY SPEED DATE SESSIONS

Room:

SALON CLAIRE

Time:

09:00 - 15:30

Representatives of the pharmaceutical industry are available throughout the day to answer all your questions. Meet them during the Tuesday morning session or for a speed date during the plenary breaks, lunchtime or network moments.

For PhD's orientating for career opportunities within the industry and have no idea what kind of choices they have and what Industry expect from them we organize these speed dates.

Former fellow students who, after several years, finished their PhD, are looking for a job. Do you want to avoid a certain mismatch between PhD / Postdoc's expectations and business? The PhD / Post doc has a certain specialist knowledge and academic work experience. Working in a company involves a complicated interplay of all different actors (departments, internal / external stakeholders, matrix structure company).

Are we facing now a shocking loss of talent under the Post-Docs in the Academy? After your PhD, almost everybody can find a job outside the academy: there is hardly any unemployment at this stage.

However, it appears that the people who choose a post-doc place in academy have a challenge. Only a very small minority can stay in the academy and most of them have a moderate career path. What should researchers do to make their post-doc more attractive to industry? PhDs who are choosing to stay in academy should be aware of the challenge.

TUESDAY



ONCODE INSTITUTE: A NEW INITIATIVE AT THE CROSSROADS OF BASIC CANCER RESEARCH AND CLINICAL IMPACT

Room: AZURE
Time: 09:00 - 09:30
Speaker: Prof. Dr. G. (Geert) Kops,
Scientific Director of Oncode
Institute, and Professor of
molecular tumor cell biology at
Hubrecht Institute

Successfully combatting cancer remains a key challenge for this and future generations. It requires generating new knowledge about cancer mechanisms on a cellular level (science) as well as applying that knowledge (engineering). With this in mind, KWF, Health Holland and three ministries have joined forces to fund the new Oncode Institute. Oncode brings together excellent basic and translational cancer research groups from across the Netherlands, and teams them up with a pro-active valorization team to guide breakthrough discoveries towards clinical impact as quickly as possible. By combining Science and Engineering in one organization, Oncode aims to substantially contribute to new therapeutic solutions for cancer patients.

COST AS AN IMPORTANT ASPECT OF SUSTAINABILITY OF DRUG DEVELOPMENT

Room: AZURE
Time: 09:30 - 10:00
Speaker: Mr. Drs. B.J. (Bruno) Bruins,
Minister for Medical Care

*unforeseen political or other circumstances may change the commitment



RECEPTOR PHARMACOLOGY AND SIGNAL TRANSDUCTION

Room: BACH 1-2
Time: 10:30 - 12:30
Chairs: Martine Smit, Amalia Dolga, Ingrid Dijkgraaf
Organizing FIGON partners: Dutch Pharmacological Society (NVF), Royal Netherlands Chemical Society (KNCV), Dutch Society for Clinical Pharmacology and Biopharmacy (NVKFB)

In this session the latest research in the field of receptor pharmacology and signal transduction will be presented. It is a multidisciplinary session and different (patho) physiological processes will be discussed.

Invited lecture:

10:30 – 11:00u "Micro-pharmacokinetics": How local drug concentration influences observed binding kinetics
Prof. Dr. Steven Charlton – University of Nottingham, UK

Selected abstracts:

11:00 – 11:15 Intracellular Irreversible Probes for GPCRs: A Covalent, Negative Allosteric Modulator for CC Chemokine Receptor 2 (CCR2)
Natalia Ortiz Zacarías – Leiden University

11:15 – 11:30 A covalent antagonist for the human adenosine A3 receptor
Xue Yang – Leiden University

11:30 – 11:45 Inhibition of Src kinase signaling pathway attenuates Nonalcoholic Steatohepatitis
Dhadhang Kurniawan – University of Twente

11:45 – 12:00 HCMV-encoded US28-mediated signaling towards the Hippo pathway in glioblastoma
Tian Shu Fan – VU University, Amsterdam

12:00 – 12:15 Characterization of cancer-induced somatic mutations in the adenosine A1 receptor
Xuesong Wang – Leiden University

12:15 – 12:30 The role of 14-3-3 mediated regulation of the cancerous inhibitor of protein phosphatase 2a (CIP2A) in breast cancer cells
Hendrik H. J. Brink – VU University, Amsterdam

Indicated speaker time includes 5 minutes for discussion

TUESDAY



DELIVERING THE PROMISE OF DATA DRIVEN PERSONALIZED MEDICINE IN ONCOLOGY.

Room: BACH 3-4
Time: 10:30 - 12:30
Chair: Teun van Gelder, Erasmus MC
Organizing FIGON partners: ZonMw, Dutch Society for Clinical Pharmacology & Biopharmacy (NVKFB)

Available (genomic) data, increasing technological possibilities are promising for the future of personalized healthcare. In this session, we will paint the picture of data-driven personalized medicine in oncology. Potential hurdles to implement novel methodology and learning systems in daily clinical practice will be highlighted and support activities will be presented to facilitate integrated analysis of genomic data to improve healthcare benefits, informed decision making and research progress.

Invited lectures:

- 10:30 – 10:54 Whole genome sequencing (WGS) for a learning care system in oncology.
Edwin Cuppen - UMCU
- 10:54 – 11:18 Implementing WGS in daily clinical practice; the hurdles
Hans van Snellenberg - HMF
- 11:18 – 11:42 Hiaatanalyse Genome Sequencing
Jeroen Beliën – VUMC
- 11:42 – 12:06 National service-desk for Ethical Legal Societal Issues Personalized Medicine
Susanne Rebers - NKI
- 12:06 – 12:30 Bioinformatics in personalized medicine
Peter van der Spek - Erasmus MC

Indicated speaker time includes 5 minutes for discussion

TUESDAY



CLINICAL PHARMACOLOGY IN INFLAMMATION AND INFECTION

Room: STRAUSS
Time: 10:30 - 12:30
Chair: Rob ter Heine
Organizing FIGON partners: Dutch Society for Clinical Pharmacology and Biopharmacy (NVKFB)

The session "Clinical pharmacology in inflammation and infection" focuses on the clinical and pharmacological aspects of treatment of inflammatory and infectious diseases.

Invited lectures:

- 10:30 – 11:10 Sustainable drug development and clinical pharmacological research in neglected tropical diseases
Dr. Thomas Dorlo - Netherlands Cancer Institute, Amsterdam
- 11:10 – 11:50 The importance of drug transporters in treatment of tuberculosis
Dr. Lindsey te Brake - Radboudumc, Nijmegen

Selected abstracts:

- 11:50 – 12:10 Proof-of-pharmacology of omiganan in patients with external genital warts
Melanie Rijsbergen - Centre for Human Drug Research, Leiden
- 12:10 – 12:30 Early-life antibiotics use increases the risk of asthma and eczema: a discordant twin study.
Elise Slob - Dept. of Respiratory Medicine, Amsterdam University Medical Centers, Amsterdam

Indicated speaker time includes 5 minutes for discussion

TUESDAY



PREDICTION OF EFFECTS OF INNOVATIVE DRUGS FROM PRECLINICAL AND EARLY CLINICAL DRUG DEVELOPMENT

Room: CERISE
Time: 10:30 - 12:30
Chairs: Gerard Rongen, Joop van Gerven
Organizing FIGON partnes: Central Committee on Research Involving Human Subject (CCMO), Dutch Society for Clinical Pharmacology & Biopharmacy (NVKFB)

The development of new therapies is increasingly based on ever improving insights into the molecular basis of genetics, immunology, cell biology and many more scientific areas. This creates a wealth of targets and opportunities for diagnosis and treatments, but it also leads to shifting boundaries between disease classifications, therapeutic approaches and clinical fields. The changing landscape of drug development also poses challenges preclinical models, which are predictive of desired and adverse effects of DNA- or RNA-based drugs, cellular therapies, highly specific monoclonal antibodies etc. In this session, some of the challenges will be presented and some approaches will be discussed.

Invited lectures:

- | | |
|---------------|---|
| 10:30 – 10:55 | Why a French drug trial went horribly wrong: prediction of severe neurological adverse effects of the FAAH-inhibitor BIA 10-2474
Prof. Steven Kushner – Neurobiological Psychiatry, Erasmus Medical Center Rotterdam |
| 10:55 – 11:20 | Prediction of safety of innovative drugs from preclinical experiments
Dr. Jan Willem van der Laan – Chair Safety Working Party CHMP/EMA, MEB/CBG |
| 11:20 – 11:45 | ‘Brain on chip’ models for precision medicine
Dr. Nael Nadif Kasri –Donders Institute for Brain, Cognition, and Behaviour; Department of Human Genetics, Radboud University Medical Center Nijmegen |
| 11:45 – 12:10 | Learning by doing: totality of evidence as a principle for rational early drug development
Prof. Joop van Gerven – Chair CCMO, Centre for Human Drug Research Leiden |
| 12:10 – 12:30 | General discussion. Speaker panel and Prof. Gerard Rongen
Radboud University Medical Center Nijmegen |

Indicated speaker time includes 5 minutes for discussion



CAREER OPPORTUNITIES IN PHARMA: JOIN OUR BATTLE AGAINST INCURABLE DISEASES

Room: ROEKEL
Time: 10:30 - 12:30
Chair: Shanna Ferdinandus
Organizing FIGON partner: Association of Innovative Medicines

Every day employees in the pharmaceutical sector are committed to and passionate about transforming patients' lives by developing innovative medicines and by providing access to medical innovations for all. Treatments that were unimaginable years ago can now cure diseases or transform deadly diseases into manageable ones. Are you looking for a challenging job in which you can contribute to human health? Join our session to find out more about working in the pharmaceutical sector.

In this session, a patient representative from the HIV association will explain what it means to live with HIV and how important and urgent research and development are when it comes to new innovative medicines for incurable diseases. Furthermore, three young professionals will tell about working in the pharmaceutical industry and what kind of jobs you can expect. Lastly, there will be a speed date session in which you can meet young professionals from different pharmaceutical companies and ask them about their experiences.

Invited lecture:

- | | |
|---------------|--|
| 10:30 – 11:00 | The value of innovative medicines
Patient representative - HIV association |
| 11:00 – 11:30 | Working in the innovative pharmaceutical industry
Hugo van Brakel, Nathalie Janssen, Elianne Goedknegt – Astellas, CSL Behring, Amgen |
| 11:30 – 12:30 | Speed date sessions with young professionals from different departments in pharmaceutical companies |

TUESDAY



PHD STUDENT COMPETITION & (POSTER) PRIZE CEREMONIES

Room: AZURE
Time: 13:30 - 15:00
Speaker: Prof. Dr. H.W. (Erik) Frijlink

5 institutes have selected their best candidates to compete for the honour and the prizes: With the following candidates (in random order):

Raw cow's milk prevents the development of asthma in a murine house-dust mite induced asthma model

Suzanne Abbring, Utrecht University

The path to improved production of the antimalarial artemisinin

Ingy Abdallah, Groningen University Institute for Drug Exploration (GUIDE)

Nanobodies targeting HCMV-encoded receptor US28 as modulators of US28 function and means to eradicate US28-expressing cells.

Timo de Groof, Amsterdam Institute for Molecules, Medicines and Systems (AIMMS)

Long-lasting small interfering RNA targeting angiotensinogen induces a robust and durable antihypertensive effect

Estrellita Uijl, Erasmus Medical Center, Rotterdam

Kick-starting drug development; translational systems pharmacology using innovative zebrafish experiments and advanced computational modelling

Rob van Wijk, Leiden Academic Center for Drug Research, (LACDR)

TUESDAY



GUIDANCE OF PATIENTS TAKING PART IN A TRIAL (IN THE ONCOLOGY)

Room: AZURE
Time: 15:30 - 16:00
Speaker: Prof. J.B. (Judith) Prins

ACALABRUTINIB: FROM BENCH TO BEDSIDE

Room: AZURE
Time: 16:00 - 16:30
Speaker: Dr. A. (Allard) Kaptein,
Acerta Pharma

Allard Kaptein is one of the founders of Acerta Pharma. Acerta Pharma is a leader in the field of covalent binding technology and is applying this technology to create novel, highly selective therapies for haematology oncology.

In the presentation the development of the company Acerta Pharma from a startup with a drug candidate with preclinical data, to a majority owned subsidiary of AstraZeneca with a drug approved by the FDA in less than 5 years, will be discussed.

The drug (acalabrutinib) was approved October 31st, 2017 by the FDA for previously treated mantle cell lymphoma patients. In the remainder of the presentation preclinical data for acalabrutinib regarding potency and selectivity will be presented as well as results from the clinical study in mantle cell lymphoma patients that were the base for the approval of the new drug application by the FDA.



HTA EXPERT / ECONOMIC SUSTAINABILITY; VISION FROM THE HTA / SCIENCE

Room: AZURE
Time: 16:30 - 17:00
Speaker: Prof. Dr. M.J. (Maarten) Postma,
University of Groningen

Recent Health Technology Assessments (HTAs) of innovative oncology drugs have illustrated the limitations of the conventional HTA-approach. These and other drugs have posed major challenges to HTA-agencies in almost all EU-countries as well as to the respective Ministries of Health that subsequently had to act on the assessments. Various issues seem to play a role here. Notably, as one main criterium in HTA, cost-effectiveness renders much higher ratios than previously encountered and cost-effectiveness appears to be inadequately aligned with affordability and budget impact. Furthermore, the conventional indication-based HTA seems to contrast the generic mechanism of action over various types and stages of cancer, often providing a rationale for genetics/proteomics- rather than indication-based treatment. Also, whereas HTA of pharmaceuticals seems well developed, that

of potentially related companion diagnostics, such as genetic tests and platforms, is not. Perceived high and non-transparent pricing of pharmaceutical products presents yet an additional issue.

As a response, already new criteria seem to have emerged in the HTA-methodology, functioning as adjustment factors in, for example, cost-effectiveness analysis.

Notably, fair innings arguments, severity, rarity and equity are now often considered in this respect, within a more Multi-Criteria Decision Analytic (MCDA) type of approach. Also, Managed Entry Agreements (MEAs) are often seen as a partial solution for the issues introduced above. Whereas they are on the rise in many other countries, applications of MEAs are staggering in The Netherlands. Also, often MEAs appear to be just "poorly" financial based rather than reflecting a "richer" form of an outcomes-based scheme. Next to potentially reviving MEAs in the Dutch context, further initiatives are needed. These could include the alignment of HTA-methodologies applied to drugs and diagnostics and their integrative analysis, extensive HTA-assessments anticipating on drug applications over various stages and indications (horizon scanning), adaptive HTA-pathways rather than one-off assessments and enhancement of transparency of pharma pricing, i.e. cost-based next to value-based assessments.

TUESDAY



PRIX GALIEN AWARDS 2018

(only pre-registered delegates, limited seats available)

Room: AZURE
Time: 17:00 - 21:35
Chair: Prof. Dr. A.H. Jan Danser

- 17:00 – 18:00 Reception, drinks and appetizer
- 18:00 – 18:15 Welcome & Video compilation 25 years Prix Galien Netherlands
- 18.15 – 18:45 *'Stem Cells, Mini-organs and Personalized Medicine'* by prof. dr. Hans Clevers, Professor of Molecular Genetics at the Hubrecht Institute, Director Research of the Princess Máxima Centre, Utrecht
- 18.45 – 19:10 Introduction nominees Prix Galien Research Award.
Announcement of the winner of the **Prix Galien Research Award 2018** by chair prof. dr. Jan Danser
- 19.10 – 19:40 Main course
- 19.40 – 20:10 *'Medicines that work'* by prof. dr. Sander van Deventer, Operating Partner, Forbion; CSO, UniQure; Professor of Translational Gastro-enterology, LUMC
- 20.10 – 20:30 Introduction candidates Prix Galien MedTech Award.
Announcement of nominees and final winner of the **Prix Galien MedTech Award 2018** by jury chair prof. dr. Marlies Schijven
- 20.30 – 20:55 Dessert
- 20.55 – 21:15 Introduction candidates Prix Galien Pharmaceutical Award.
Announcement of nominees and final winner of the **Prix Galien Pharmaceutical Award 2018** by jury chair prof. dr. Jan Danser
- 21.15 Closing and reception



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