



Curriculum Vitae

Personal information Peter Theunissen

Work experience

1. Employer: CBG_MEB
 - Start date: 022015
 - End date:
 - Position: Non_clinical Assessor
 - Activities: Assessor of non_clinical pharmacodynamics, toxicology and pharmacokinetics of pharmaceuticals. Expert in 3Rs, reproductive and developmental toxicology, New Approach Methods (NAMs) and database analysis.
 - Country: Netherlands
2. Employer: Radboud University Nijmegen
 - Start date: 062021
 - End date:
 - Position: Visiting Scientist
 - Activities: Regulatory opportunities and challenges to improve non_clinical requirements in drug development. Co_promotor PhD_student
 - Country: Netherlands
3. Employer: Dutch Society of Toxicology
 - Start date: 062014
 - End date: 12 June 2023
 - Position: Treasurer
 - Activities: Treasurer and boardmember of the Dutch Society of Toxicology (Nederlandse Vereniging voor Toxicologie).
 - Country: Netherlands
4. Employer: RIVM / Hogeschool Utrecht
 - Start date: 022012
 - End date: 122014
 - Position: Postdoctoral Researcher
 - Activities: Alternatives for Animal Testing in Developmental Toxicology Building a comprehensive database and performing an analysis on the need of in vivo developmental toxicity testing on both rat and rabbit in pharmaceutical industry. This international project, performed in collaboration with RIVM, CBG_MEB and ILSI_HESI_DART, aims to investigate the similarities and differences in prediction of developmental toxicity in rat and rabbit, to reduce animal testing and design a more intelligent testing strategy for developmental toxicity testing. Improve prediction of the embryonic stem cell test by introducing novel molecular endpoints.
 - Country: Netherlands
5. Employer: Maastricht University / RIVM
 - Start date: 092007
 - End date: 122011
 - Position: PhD_Student
 - Activities: Development of an alternative toxicogenomics based testmodel for (neuro_)developmental toxicity screening on neural differentiation of murine embryonic stem cells. Promotors: Prof. Dr. Aldert Piersma and Prof. Dr. Jos Kleinjans Dissertation Defense: 1 March 2013
 - Country: Netherlands
6. Employer: TNO Quality of Life
 - Start date: 022007
 - End date: 072007
 - Position: Researcher
 - Activities: _ Writing scoping reports on potential reproductive toxic compounds and potential carcinogenic compounds for the Dutch Health Council _ Writing report on the reproductive toxic effects of hydrogen_ and sodium fluoride for the Dutch Health Council _ Exploratory research on future development and implementation of in vitro developmental toxicity test systems within the department Toxicology and Applied Pharmacology
 - Country: Netherlands

Education and training

1. Subject: Radboud University Nijmegen
 - Start date: 092001
 - End date: 122006
 - Qualification: MSc. in Toxicology
 - Organisation: Toxicology, Reproduction and Embryo_Fetal Development, Neuropharmacology and 3Rs/Alternatives to Animal Testing
 - Country: Netherlands
2. Subject: Maastricht University
 - Start date: 022007
 - End date: 122011
 - Qualification: PhD. in Toxicology
 - Organisation: Toxicology, Developmental toxicology, Stem Cells, In vitro assays, Transcriptomics, Big data analysis
 - Country: Netherlands
3. Subject: Postdoctoral Education in Toxicology

- Start date: 072009
- End date: 032013
- Qualification: Postdoctoral Education in Toxicology
- Organisation: Cellular Toxicology Ecotoxicology Epidemiology Medical and Forensic Toxicology Molecular Toxicology Reproductive Toxicology Risk Assessment Toxicogenomics Regulatory Toxicology
- Country: Netherlands

Additional information

Publications

Non-clinical considerations for supporting accelerated inclusion of pregnant women in clinical trials for HIV Rick Greupink, Hedwig van Hove, Felix Mhlanga, Peter Theunissen, Angela Colbers. *J Int AIDS Soc.* 2022 Jul; 25(Suppl 2): e25914. Applicability of organ_on_chip systems in toxicology and pharmacology. Schneider MR, Oelgeschlaeger M, Burgdorf T, van Meer P, Theunissen P, Kienhuis AS, Piersma AH, Vandebriel RJ. *Crit Rev Toxicol.* 2021 Jul;51(6):540-554. doi: 10.1080/10408444.2021.1953439. Epub 2021 Aug 31. Animal-free applications in the development of cell-based therapies Peter van Meer, Peter Theunissen, Tineke van den Hoorn, Carla Herbets, Jan Willem van der Laan. *Br J Clin Pharmacol.* 2020 Sep 15. doi: 10.1111/bcp.14544. Testing developmental toxicity in a second species: are the differences due to species or replication error? raakhuis HM, Theunissen PT, Slob W, Rorij E, Piersma AH. *egul Toxicol Pharmacol.* 2019 Oct;107:104410. doi: 10.1016/j.yrtp.2019.104410. Epub 2019 Jun 19. Analysis of exposure margins in developmental toxicity studies for detection of human teratogens. Andrews PA, Blanset D, Costa PL, Green M, Green ML, Jacobs A, Kadaba R, Lebron JA, Mattson B, McNerney ME, Minck D, Oliveira LC, Theunissen PT, DeGeorge JJ. *Regul Toxicol Pharmacol.* 2019 Jul;105:62-68. doi: 10.1016/j.yrtp.2019.04.005. Epub 2019 Apr 11. Comparison of rat and rabbit embryo_fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects. Theunissen PT, Beken S, Beyer BK, Breslin WJ, Cappon GD, Chen CL, Chmielewski G, De Schaepdrijver L, Enright B, Foreman JE, Harrouk W, Hew KW, Hoberman AM, Hui JY, Knudsen TB, Laffan SB, Makris SL, Martin M, McNerney ME, Siezen CL, Stanislaus DJ, Stewart J, Thompson KE, Tornesi B, Van der Laan JW, Weinbauer GF, Wood S, Piersma AH. *Crit Rev Toxicol.* 2016 Nov;46(10):900-910. Comparing rat and rabbit embryo_fetal developmental toxicity data for 379 pharmaceuticals: on systemic dose and developmental effects. Theunissen PT, Beken S, Beyer B, Breslin WJ, Cappon GD, Chen CL, Chmielewski G, de Schaepdrijver L, Enright B, Foreman JE, Harrouk W, Hew KW, Hoberman AM, Y Hui J, Knudsen TB, Laffan SB, Makris SL, Martin M, McNerney ME, Siezen CL, Stanislaus DJ, Stewart J, Thompson KE, Tornesi B, Van der Laan JW, Weinbauer GF, Wood S, Piersma AH. *Crit Rev Toxicol.* 2016 Oct 21:1-13. Comparison of gene expression regulation in mouse_and human embryonic stem cell assays during neural differentiation and in response to valproic acid exposure. Schulpen SH, Theunissen PT, Pennings JL, Piersma AH. *Reprod Toxicol.* 2015 Aug 15;56:77-86. TOWARD A COMPARATIVE RETROSPECTIVE ANALYSIS OF RAT AND RABBIT DEVELOPMENTAL TOXICITY STUDIES FOR PHARMACEUTICAL COMPOUNDS. Theunissen PT, Beken S, Cappon G, Chen C, Hoberman A, van der Laan JW, Stewart J, Piersma AH. *Reprod Toxicol.* 2014 Aug; 47: 27-32. □ DYNAMIC CHANGES IN ENERGY METABOLISM UPON EMBRYONIC STEM CELL DIFFERENTIATION SUPPORT DEVELOPMENTAL TOXICANT IDENTIFICATION. van Dartel DA, Schulpen SH, Theunissen PT, Bunschoten A, Piersma AH, Keijer J. *Toxicology.* 2014 Oct 3;324:76-87. VALPROIC ACID-INDUCED GENE EXPRESSION RESPONSES IN RAT WHOLE EMBRYO CULTURE AND COMPARISON ACROSS IN VITRO DEVELOPMENTAL AND NON-DEVELOPMENTAL MODELS. Tonk EC, Robinson JF, Verhoef A, Theunissen PT, Pennings JL, Piersma AH. *Reprod Toxicol.* 2013 Nov;41:57-66 □ COMPLEMENTARY DETECTION OF EMBRYOTOXIC PROPERTIES OF SUBSTANCES IN THE NEURAL AND CARDIAC EMBRYONIC STEM CELL TESTS (ESTN AND ESTC). Theunissen PT, Pennings JL, van Dartel DAM, Robinson JF, Kleinjans JC, Piersma AH. *Toxicol Sci.* 2013 Mar;132(1):118-30. □ AN OPTIMIZED GENE SET FOR TRANSCRIPTOMICS-BASED NEURODEVELOPMENTAL TOXICITY PREDICTION IN THE NEURAL EMBRYONIC STEM CELL TEST (ESTN). Pennings JL, Theunissen PT and Piersma AH. *Toxicology.* 2012 Oct 28;300(3):158-67. □ COMPOUND-SPECIFIC EFFECTS OF DIVERSE NEURODEVELOPMENTAL TOXICANTS ON GLOBAL GENE EXPRESSION IN THE NEURAL EMBRYONIC STEM CELL TEST (ESTN). Theunissen, PT, Robinson JF, Pennings JLA, Herwijnen MH, Kleinjans JCS and Piersma, AH. *Toxicol. and Appl. Pharmacol.* 2012: Aug ; 262(3):330-40. □ THE EMBRYONIC STEM CELL TEST AND ITS APPLICATION IN ALTERNATIVE TOXICITY TESTING STRATEGIES. Theunissen, PT and Piersma, AH. *Frontiers in Bioscience*, 2012: Jan; 17:1965-75. □ DOSE-RESPONSE TOXICOGENOMIC EVALUATION OF VALPROIC ACID, CYPROCONAZOLE AND HEXACONAZOLE IN THE NEURAL EMBRYONIC STEM CELL TEST (ESTN). Theunissen, PT, , Robinson JF, Pennings, JLA Claessen SMH, De Jong E, Kleinjans JCS and Piersma, AH *Toxicological Sciences. Toxicol Sci.* 2012: Feb; 125(2):430-8. □ COMPARISON OF MEHG-INDUCED TOXICOGENOMIC RESPONSES ACROSS IN VIVO AND IN VITRO MODELS USED IN DEVELOPMENTAL TOXICOLOGY. Robinson JF, Theunissen PT, van Dartel DA, Jeroen Pennings JL, Faustman EM, Piersma AH. *Reproductive Toxicology*, 2011: Sep;32(2):180-8. □ TIME RESPONSE EVALUATION BY TRANSCRIPTOMICS OF METHYLMERCURY EFFECTS ON NEURAL DIFFERENTIATION OF MURINE EMBRYONIC STEM CELLS. Theunissen, PT, Robinson JF, Pennings JLA, Claessen SMH, Kleinjans JCS and Piersma, AH. *Toxicological Sciences*, 2011: Aug;122(2):437-47. □ AN ABBREVIATED PROTOCOL FOR MULTI-LINEAGE NEURAL DIFFERENTIATION OF MURINE EMBRYONIC STEM CELLS AND ITS PERTURBATION BY METHYL-MERCURY. Theunissen, PT, Schulpen SH, Van Dartel DA, Hermsen SA, van Schooten FJ, and Piersma, AH. *Reproductive Toxicology*, 2010: 29(4):383-92. □ HYDROGEN FLUORIDE AND SODIUM FLUORIDE: EVALUATION OF THE EFFECTS ON REPRODUCTION, RECOMMENDATION FOR CLASSIFICATION. Health Council of the Netherlands. Report preparation by Theunissen PT, Wolterbeek APM. The Hague: Health Council of the Netherlands, 2009; publication no. 2009/OSH04. □ DNA-REPAIR-DEFICIENT RAD54/RAD54B MICE ARE MORE SENSITIVE TO CLASTOGENS THAN WILD-TYPE MICE. Mahabir AG, Schaap M, Theunissen PT, van Benthem J, Essers J, de Vries A, Hendriksen CF, van Steeg H. *Toxicology Letters.* 2008;183 (1-3):112-7. NEURODEVELOPMENTAL TOXICITY DETECTION BY TRANSCRIPTOMICS IN AN EMBRYONIC STEM CELL DIFFERENTIATION ASSAY. Theunissen PT. February 2013. ISBN: 978-94-6203-277-4. Promotors en Co-promotor: Prof. Dr. AH Piersma, Prof. Dr. JC Kleinjans, Dr. JL Pennings. EMBRYONIC STEM CELL TEST (EST): MOLECULAR ENDPOINTS TOWARDS HIGH-THROUGHPUT ANALYSIS OF CHEMICAL EMBRYOTOXIC POTENTIAL, CHAPTER 19. Theunissen PT, de Jong E, Robinson JF, Piersma AH. In: Steinberg P, editor. *High-throughput screening methods in toxicity testing.* Wiley & Sons, inc. April 2013. ISBN: 978-1-1180-65631.

Projects

Development and maintenance of an embryo_fetal developmental toxicity study database (2012_present). MEB/RIVM. Regulatory opportunities and challenges to improve non-clinical requirements in drug development Co-promotor PhD-student at Radboud University Nijmegen. (2021_present) Cross-agency pilot for implementation of SEND in assessment at national competent authorities the Netherlands (MEB), Germany (BfARM), Belgium (FAMHP), Austria (AGIS) and Switzerland (SwissMedic). (2019-present) EMA: 3RsWP member (2022_present) _ NCWG_PDCCO expert. (2020-2022). _ Lifecycle Regulatory Submissions Raw Data project - steering group member (2021-present). _ Re-use of animal data in regulatory submissions drafting group _ Upgrading of existing regulatory concepts to avoid duplication of animal studies and facilitate reuse of data - drafting group member (2021-2022). HESI-DART Technical committee projects: _ Developmental toxicity second species database project (2012-2017) _ New Approach Methods (NAMs) in developmental toxicity project (2020-ongoing) _ DARTable genome project (2020-ongoing) _ Concordance between preliminary EFD studies and the subsequent definitive studies Scoping group (2021-present) _ Reducing NHP use in DART assessment (2022-present) WHO_IMPAACT: Approaches to Enhance and Accelerate Study of New Drugs for HIV and Associated Infections in Pregnant Women. Member of workgroup on nonclinical considerations for supporting accelerated inclusion of pregnant women in clinical trials for HIV. (2020-2022) ConcePTION consortium _ Building an ecosystem for better monitoring and communicating safety of medicines use in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation. Workpackage 7.9 Create a databank of reprotox data (RIVM/MEB). (2018_present). Introducing the embryonic stem cell test (EST) at the University of Applied Sciences Utrecht and improve prediction of the EST by introducing novel molecular endpoints. (RIVM/University of Applied Sciences Utrecht)(2012-2014). Development of an alternative toxicogenomics based testmodel for (neuro_)developmental toxicity screening on neural differentiation of murine embryonic stem cells. (PhD track, 2007-2011, RIVM and University of Maastricht). Writing scoping reports on potential reproductive toxic compounds and potential carcinogenic compounds for the Dutch Health Council (TNO, 2007) Writing report on the reproductive

toxic effects of hydrogen_ and sodium fluoride for the Dutch Health Council (TNO, 2007) Exploratory research on future development and implementation of in vitro developmental toxicity test systems within the department Toxicology and Applied Pharmacology (TNO, 2007) Development of in vivo and in vitro genotoxicity screening methods using the LacZ reporter gene. (RIVM, 2006). Development and prevalidation of an in vitro model to evaluate the reproductive toxic effect of compounds on sperm, using Computer Assisted Sperm Analysis (CASA) under the ECVAM REPROTECT project. (TNO, 2005_2006). Functional and behavioral characterization of a D1 Receptor Mutant Rat (Radboud University Nijmegen, 2005). Patents METHOD FOR DETERMINING THE NEURODEVELOPMENTAL TOXICITY OF A COMPOUND IN VITRO. Theunissen, P. T., Pennings, J.L., and Piersma, A. H., inventors; University of Maastricht, National Institute for Public Health and the Environment (RIVM), assignee. European patent EP 12164410.8. October 23, 2013. METHOD FOR DETERMINING THE NEURODEVELOPMENTAL TOXICITY OF A COMPOUND IN VITRO. Theunissen, P. T., Pennings, J.L., and Piersma, A. H., inventors; University of Maastricht, National Institute for Public Health and the Environment (RIVM), assignee. European patent EP 11163980.3 October 31, 2012 ; International patent number WO2012/146496. November 1, 2012.

Memberships

S5(R3) EWG Member, EC, Europe (2016_2020) S5(R4) Maintenance procedure EWG Member (EC, Europe (2020_present) 3RsWP member, EMA, Europe (2022_present) NCWG_PDCO member, EMA, Europe (2020_2022) Treasurer and Board member of the Netherlands Society of Toxicology (NVT) (2014_present) Board member of the Pharmaceutical Toxicology Specialty section of the Netherlands Society of Toxicology (NVT) (2013_2020) Organizer of the Conference of the Dutch Society of Toxicology (NVT) and PhD_days (2009, 2014_2022) Member of the Dutch Toxicology Society (2004_present) Member of the European Teratology Society (2014_present)

Other Relevant Information

Awards Award for best Dutch toxicology PhD_Thesis 2014 (Joep van den Bercken prijs) awarded by Dutch Society of Toxicology (NVT) Finalist for the STW Simon Stevin Gezel prize for Most innovative Dutch PhD research 2014 1 ½ year Research Grant from ILSI_HESI_DART for investigating the need of the 2nd species in developmental toxicity testing for pharmaceuticals (2013_2014) Award for best oral presentation at 2011 Dutch Society of Toxicology (NVT) congress