



## Curriculum Vitae

Personal information **Jan Willem van der Laan**

### Work experience

---

1. Employer: National Institute for Public Health and the Environment
  - Start date: 011980
  - End date: 091990
  - Position: Head Psychopharmacology
  - Activities: Research on dependence on opiates and benzodiazepines, pharmacological assessor for Medicines Evaluation Board
  - Country: Netherlands
2. Employer: Erasmus University Rotterdam
  - Start date: 051977
  - End date: 121979
  - Position: Ph.D. Student
  - Activities: Neurochemical and animal behavioural research
  - Country: Netherlands
3. Employer: National Institute for Public Health and the Environment
  - Start date: 101990
  - End date: 052011
  - Position: Head Medicines Assessment Group
  - Activities: Senior assessor Pharmacology and Toxicology Group leader for assessment of pharmacological/toxicological part of the dossier, Manager Teratology Information Service
  - Country: Netherlands
4. Employer: Medicines Evaluation Board
  - Start date: 062011
  - End date:
  - Position: Senior Assessor Pharmacology/Toxicology
  - Activities: International Contribution to guideline development and assessment of nonclinical part of the dossiers. Coaching research in relevant areas.
  - Country: Netherlands

### Education and training

---

1. Subject: Erasmus University Rotterdam
  - Start date: 051977
  - End date: 091981
  - Qualification: Ph.D. Thesis
  - Organisation: Research and training in Neuropharmacology, Neurobiochemistry Writing a thesis
  - Country: Netherlands
2. Subject: University of Wageningen/Utrecht
  - Start date: 101990
  - End date: 101992
  - Qualification: Post\_doctoral courses on Toxicology
  - Organisation: General Toxicology, Pathology
  - Country: Netherlands

### Additional information

---

#### Publications

2011 Van der Laan JW. The Challenge and Satisfaction of Globalization. A Personal Perspective. DIA Global Forum 2011; 3: 21\_24 2012 De Jong HJJ, Klungel OH, L. van Dijk L, Vandebriel RJ, Leufkens HGM, Cohen Tervaert JW, Van der Laan JW, Van Loveren H. Use of statins is associated with an increased risk of Rheumatoid Arthritis, *Annals Rheum. Disease* 2012; 71: 648\_654 2012 Van der Laan JW, Chapin RE, Haenen B, Jacobs AC, Piersma AH. Testing Strategies for Embryo\_Fetal Toxicity of Human Pharmaceuticals. Animal models vs in vitro approaches. A workshop report. *Regulat. Toxicol. Pharmacol.* 2012; 63: 115\_123 2012 Jacobs A, Van der Laan JW. Regulatory aspects: Pharmaceuticals, Medical Devices, Food Additives: Minipigs and Global Safety Regulations. In: *The Minipig in Biomedical Research.* (eds. McNulty PA, Dayan AD, Gandrup NC, Hastings KL), CRC Press, Taylor & Francis Group, London. 2012, pp.565\_571 2013 Van der Laan JW, DeGeorge JJ, The International Conference on Harmonisation: History of Safety Guidelines. In: *Global Approach in Safety Testing* (Van der Laan JW, DeGeorge JJ, eds). *Advances in the Pharmaceutical Sciences Series 5*, pp.1\_12 2013 Van der Laan JW, DeGeorge JJ, Sistare F, Moggs J. Toward Moe Scientific Relevance in Carcinogenicity Testing. In: *Global Approach in Safety Testing* (Van der Laan JW, DeGeorge JJ, eds). *Advances in the Pharmaceutical Sciences Series 5*, pp.37\_75 2013 Vandebriel RJ, De Jong HJJ, Gremmer ER, Klungel OH, Cohen Tervaert JW, Slob W, van der Laan JW, van Loveren H. Reply: Statins accelerate the onset of collagen type II\_induced arthritis in mice. *Arthritis Research & Therapy* 2013; 15: 403 2013 Vandebriel RJ, De Jong HJJ, Gremmer ER, Klungel OH, Cohen Tervaert JW, Slob W, van der Laan JW, van Loveren H. Reply: Statins accelerate the onset of collagen type II\_induced arthritis in mice. *Arthritis Research & Therapy* 2013; 15: 403 2013 Van der Laan JW, Hastings K. The ICH: History and Nonclinical Guidances. In: *Nonclinical Safety Assessment. A Guide to International Pharmaceutical Regulations* (Brock W, Hastings K, McGown KM, eds). pp. 17\_26 2013 Woolley A, Van der Laan JW. European Pharmaceutical Regulation – Nonclinical Testing Requirements. In: *Nonclinical Safety Assessment. A Guide to International Pharmaceutical Regulations* (Brock W, Hastings K, McGown KM, eds). pp. 79\_98 2013 Darrell R. Boverhof, Greg Ladics, Bob Luebke, Jane Botham, Emanuela Corsini, Vicki Dellarco, Ellen Evans, Dori Germolec, Michael Holsapple, Scott E Loveless, Hatian Lu, Jan Willem van der Laan, Kimber White, Yung Yang. Approaches and Considerations for the Assessment of Immunotoxicity for Environmental Chemicals: A Workshop Summary. 2013 Nov 23;68(1):96\_107 2013 Sathish JG, Sethu S, Bielsky MC, de Haan L,

French NS, Govindappa K, Green J, Griffiths CE, Holgate S, Jones D, Kimber I, Moggs J, Naisbitt DJ, Pirmohamed M, Reichmann G, Sims J, Subramanyam M, Todd MD, Van Der Laan JW, Weaver RJ, Park BK. Challenges and approaches for the development of safer immunomodulatory biologics. *Nat Rev Drug Discov.* 2013 Apr;12(4):306\_24. 2013 Van Meer PJ, Kooijman M, van der Laan JW, Moors EH, Schellekens H. The value of non\_human primates in the development of monoclonal antibodies. *Nat Biotechnol.* 2013, 31(10):882\_3 2014 ter Braak B., Siezen CLE, Kannegieter N, Koedoot E, Van de Water B, Van der Laan JW. Classifying the adverse mitogenic mode of action of insulin analogues using a novel mechanism\_based genetically engineered human breast cancer cell panel. *Arch. Toxicol.* DOI 10.1007/s00204\_014\_1201\_2 2014 Annys E, Billington R, Clayton R, Dieter Bremm K, Graziano M, McKelvie J, Ragan I, Schwarz M, Van der Laan JW, Wood C, Öberg M, Wester P, Woodward KN. Advancing the 3Rs in Regulatory Toxicology \_ Carcinogenicity Testing: Scope for Harmonisation and Advancing the 3Rs in Regulated Sectors of the European Union. *Regul. Toxicol.Pharmacol.* 2014; 69(2):234\_42 2014 Theunissen PT, Beken S, Cappon GD, Chen C, Hoberman AM, Van der Laan JW, Stewart J, Piersma AH: Toward a comparative retrospective analysis of rat and rabbit developmental toxicity studies for pharmaceutical compounds. *Reproductive Toxicology* 2014; 47: 27\_32 2014 Van Aerts LAGJM, DeSmet K, Reichman G, van der Laan JW, Schneider CK. Biosimilars entering the clinic without animal studies: A paradigm shift in the European Union. *MAbs.* 2014 Aug 5;6(5). [Epub ahead of print] 2015 van der Laan JW, Herberths CA, Jones DJ, Thorpe S, Stebbings R, Thorpe R. The Nonclinical evaluation of Biotechnology\_derived Pharmaceuticals, Moving on after the TeGenero Case. In: *Molecular Immunotoxicology*, Eds. Emanuela Corsini & Henk van Loveren. Wiley\_VCH Verlag. Pp.189\_207 2015 B. ter Braak, C.L.E. Siezen, E.N. Speksnijder, E. Koedoot, H. van Steeg, D.C.F. Salvatori, B. van de Water, J.W. van der Laan (2015) Mammary gland tumor promotion by chronic administration of IGF1 and the insulin analogue AspB10 in the p53R270H/+WAPCre mouse model, *Breast Cancer Research* (accepted for publication) 2015 Van der Laan JW, Gould S, Tanir J (2015) Safety of Adjuvants: Focus on Autoimmunity. *Vaccines*, 33(13):1507\_14 2015 Bronsveld H, Ter Braak B, Karlstad O, Vestergaard P, Starup\_Linde J, Bazelier MT, De Bruin ML, de Boer A, Siezen CLE, van de Water B, van der Laan JW, Schmidt MK (2015) Treatment with insulin (analogues) and breast cancer risk in diabetics; a systematic review and meta\_analysis of in vitro, animal and human evidence. *Breast Cancer Research* 17(1):100. doi: 10.1186/s13058\_015\_0611\_2. 2015 Ter Braak SJ, Wink S, Koedoot E, Pont C, Siezen CLE, van der Laan JW, van de Water B (2015) Alternative signaling network activation through different insulin receptor family members caused by promitogenic antidiabetic insulin analogues in human mammary epithelial cells. *Breast Cancer Research* 17, 97. doi: 10.1186/s13058\_015\_0600\_5 2015 Ramirez T, Beken S, Chlebun M, Ellis G, Griesinger C, De Jonghe S, Manou I, Mehling A, Reisinger K, Rossi LH, van Benthem J, van der Laan JW, Weissenhorn R, Sauer UG (2015) Knowledge sharing to facilitate regulatory decision\_making in regard to alternatives to animal testing: Report of an EPAA workshop. *Regulatory Toxicology and Pharmacology* 73, 210\_226 2016 Beken S, Kasper P, van der Laan JW (2016) Regulatory acceptance of alternative methods in the development and approval of pharmaceuticals. In: *Validation of Alternative Methods for Toxicity testing*. Eds. Chantra Eskes, Maurice Whelan. Springer AG. *Adv.Exp.Med.Biol* 2016, 856, 33\_64. DOI 10.1007/9783\_3\_319\_33826\_2\_3 2016 Van der Laan JW, Kasper P, Silva Lima B, Jones DR, Pasanen M (2016) Critical analysis of carcinogenicity study outcomes. Relationship with pharmacological properties, *Critical Reviews in Toxicology*, DOI: 10.3109/10408444.2016.1163664 2016 Luijten M, Olthof ED, Hakkert BC, Rorije E, van der Laan JW, Woutersen RA, van Benthem J (2016): An integrative test strategy for cancer hazard identification, *Critical Reviews in Toxicology*, DOI: 10.3109/10408444.2016.1171294 2016 Woutersen RA, Soffers AE, Kroese ED, Krul CA, van der Laan JW, van Benthem J, Luijten M. (2016) Prediction of carcinogenic potential of chemicals using repeated\_dose (13\_week) toxicity data. *Regul Toxicol Pharmacol.* 2016 Sep 8;81:242\_249. doi: 10.1016/j.yrtph.2016.09.003. 2016 Van der Laan JW, Buitenhuis W, Wagenaar L, Soffers AEMF, Van Someren EP, Krul CAM, Woutersen RA (2016) Prediction of the carcinogenic potential of human pharmaceuticals using repeated dose toxicity data and their pharmacological properties. *Frontiers in Medicine*, 2016, 3:45. doi: 10.3389/fmed.2016.00045 2016 Theunissen PT, Beken S, Beyer BK, Breslin WJ, Cappon GD, Chen CL, Chmielewski G, De Schaepdrijver L, Enright B, Foreman JE, Harrouk W, Hew K\_W, Hoberman AM, Hui JY, Knudsen TB, Laffan SB, Makris SL, Martin M, Mc Nerney ME., Siezen CLE., Stanislaus DJ, Stewart J, Thompson KE, Tornesi B, Van der Laan JW, Weinbauer GF, Wood S, Piersma AH.( 2016) Comparison of rat and rabbit embryo-fetal developmental toxicity data for 379 pharmaceuticals: on the nature and severity of developmental effects. *Crit Rev Toxicol.* 2016 Nov;46(10):900\_910 DOI: 10.1080/10408444.2016.1224807 2016 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, Mc Nerney ME, Siezen CL, Stanislaus DJ, Stewart J, Thompson KE, Tornesi B, Van der Laan JW, Weinbauer GF, Wood S, Piersma AH. (2016) Comparing rat and rabbit embryo\_fetal developmental toxicity data for 379 pharmaceuticals: on systemic dose and developmental effects. *Crit Rev Toxicol.* 2016 Oct 21:1\_13. 2017 Van den Brink WJ, Emerenciana A, Bellanti F, Della Pasqua O, Van der Laan JW (2017) Prediction of thyroid C\_cell carcinogenicity after chronic administration of GLP1\_R agonists in rodents. *Toxicology and Applied Pharmacology*, 2017; 320: 51\_59 DOI information: 10.1016/j.taap.2017.02.010 2017 Sewell F, Chapman K, Couch J, Dempster M, Heidel S, Loberg L, Maier C, MacLachlan TK, Todd M, Van der Laan JW (2017) Challenges and opportunities for the future of monoclonal antibody development: Improving safety assessment and reducing animal use, *mAbs*, 9:5, 742\_755, DOI: 10.1080/19420862.2017.1324376 2017 Van der Laan JW, Duijndam BHA, Van den Hoorn T, Woutersen RA, Van de Water B. Changing the field of carcinogenicity testing of human pharmaceuticals by emphasizing mode of action. *Current Opinion in Toxicology* 2017, 3:55-61 DOI: 10.1016/j.cotox.2017.06.004 2018 Braakhuis H, Slob W, Olthof E, Wolterink G, Zwart E, Gremmer E, Rorije E, van Benthem J, Woutersen RA, van der Laan JW, M. Is current risk assessment of non\_genotoxic carcinogens protective? *Crit. Review. Toxicol.* 2018 48:6, 500\_511, DOI: 10.1080/10408444.2018.1458818 2018 Ponzano, S., Blake, K., Bonelli, M., Enzmann, H., on behalf of the European Medicines Agency Committee for Human Medicinal Products "First\_in\_Human Guideline Drafting Group." Promoting safe early clinical research of novel drug candidates: a European Union Regulatory Perspective. *Clin. Pharmacol. Ther.* 103,564-566 (2018). 2019 Pieters R, Van der Laan JW, Van Loveren H., *Immunotoxicology* 2019. In: Nijkamp FP, Parnham MJ (eds). Birkhäuser, Basel. Principles of Immunopharmacology, 4th edition, 2019, pp. xxx\_xxx, in press 2019 Van der Laan JW, Benson CT, Janssens W, Bos J, Stahl E, Brady JT, Wändel Liminga U, Corriol\_Rohou S, Forster R, Hartmann A, Pertel PE, Robertson SM, Silva\_Lima B, Malik RE, Chibout SD. Shared Learnings on the New EMA First\_in\_Human and Early Clinical Trial Guideline: Proceedings From a Dialogue Session at DIA Europe 2018. *Ther Innov Regul Sci.* 2019 May 13:2168479019843514. doi: 10.1177/2168479019843514. [Epub ahead of print] Ghalandari N, Dolhain RJEM, Hazes JWM, C., Siezen CLE, van der Laan JW, Crijns HJ, van Puijbroek EP, van der Woude CJ, The pre\_ and post\_authorisation data published by the European Medicines Agency on the use of Biologics during pregnancy and lactation. *Brit. J. Clin. Pharmacol.* 2020; 1\_11; <https://doi.org/10.1111/bcp.14145> <https://bpspubs.onlinelibrary.wiley.com/doi/abs/10.1111/bcp.14145> 2019 Sato Y, Bando H, Di Piazza M, Gowing G, Herberths CA, Jackman S, Leoni G, Libertini S, MacLachlan T, McBlane JW, Pereira Mouris L, Sharpe M, Shingleton W, Surmacz\_Cordle B, Yamamoto K, van der Laan JW, Tumorigenicity assessment of cell therapy products: The need for global consensus and points to consider. *Cytotherapy*, 2019, 21: 1095\_1111; <https://doi.org/10.1016/j.jcyt.2019.10.001> 2019 Van der Laan JW, Van Malderen K, de Jager N, Duarte D, Egger GF, Laverigne F, Roque CG, Vieira MI, Wiesner L, Carleer J. Evaluation of juvenile animal studies for pediatric CNS\_targeted compounds; a regulatory perspective. *Intern. J. Toxicol.* In press 2020 Yauk CL, Harrill AH, Ellinger\_Ziegelbauer H, van der Laan JW, Moggs J, Froetschl R, Sistare F, Pettit S. A cross\_sector call to improve carcinogenicity risk assessment through use of genomic methodologies. *Regul. Toxicol. Pharmacol.* 110 (2020) 104526 Giannakou C, Park MVDZ, Bosselaers IEM, de Jong WH, van der Laan JW, van Loveren H, Vandebriel RJ, Geertsma RE. Non\_clinical regulatory immunotoxicity testing of nanomedicinal products proposed strategy and possible pitfalls. *Nanomed Nanobiotechnol.* 2020 Apr 7:e1633. doi: 10.1002/wnan.1633. [Epub ahead of print] Review. 2020 Van Meer P, Theunissen, P, Van den Hoorn T, Herberths CA, Van der Laan JW, Animal free applications in the development of cell\_based therapies. *Brit. J. Clin. Pharmacol.* DOI: 10.1111/bcp.14544 2020 Van den Hoorn T, Nakchedi T, de Wolf, ACMT, Pasmooij, AMG, van der Laan JW, Herberths CA, Mining scientific advice reports on cellular therapeutics, insight in the non\_clinical development program. *Brit. J. Clin. Pharmacol.* Accepted for publication. 2020 Luijten M, Corvi R, Mehta J, Broecker F, Corvaro M, Delrue N, Felter S, Guyton K, Haas B, Hewitt N, Hilton G, Holmes T, Jacobs MN, Jacobs A, Lamplmair F, Lewis D, Madia F, Manou I, Melching\_Kollmuss S, Schorsch F, Schutte K, Sewell F, Strupp C, Terron A, van der Laan JW, Wolf DC, Wolterink G, Woutersen R, Zvonar Z, Heusinkveld H, Braakhuis H. A mechanistic approach for cancer risk assessment of non\_genotoxic agrochemicals: Report of an EPAA workshops. *Regul. Toxicol. Pharmacol.* 118, 2020, 104789 2020 Heusinkveld H, Braakhuis H, Robin Gommans, Phil Botham, Marco Corvaro, Jan Willem van der Laan, Dick Lewis, Federica Madia, Irene Manou, Stephanie Melching\_Kollmuss, Frédéric Schorsch, Gerrit Wolterink, Ruud Woutersen, Raffaella Corvi, Jyotigna Mehta,

and Mirjam Luijten, Towards a mechanism\_based approach for the prediction of non\_genotoxic carcinogenic potential of agrochemicals. Crit. Rev. Toxicology, <https://doi.org/10.1080/10408444.2020.1841732> Duijndam BH, Goudriaan A, Van den Hoorn T, van der Stel W, Levedec S, Bouwman RJP Van der Laan JW, Van de Water B. Physiologically relevant estrogen receptor alpha pathway reporters for single cell imaging\_based carcinogenic hazard assessment of estrogenic compounds. Toxicol Sci. 2021 May 27;181(2):187\_198. doi: 10.1093/toxsci/kfab037. Van der Laan JW, Sistare FD, Ogawa K. Contributing to Replacement, Reduction and Refinement (3RS) in animal testing through harmonization of international safety guidelines. ICH 30th Anniversary Publication, pp. 31\_32 Duijndam B, Tedeschi M, van der Stel W, van den Hoorn T, van der Burg B, Bouwman P, van der Laan JW, van de Water B. Evaluation of an imaging\_based in vitro screening platform for estrogenic activity with OECD reference chemicals. Toxicol In Vitro. 2022 Jun;81:105348. doi: 10.1016/j.tiv.2022.105348. Corton JC, Mitchell CA, Auerbach S, Bushel P, Ellinger\_Ziegelbauer H, Escobar PA, Froetschl R, Harrill AH, Johnson K, Klaunig JE, Pandiri AR, Podtelezhnikov AA, Rager JE, Tanis KQ, van der Laan JW, Vespa A, Yauk CL, Pettit SD, Sistare FD. A Collaborative Initiative to Establish Genomic Biomarkers for Assessing Tumorigenic Potential to Reduce Reliance on Conventional Rodent Carcinogenicity Studies. Toxicol Sci. 2022 Jun 28;188(1):4\_16. doi: 10.1093/toxsci/kfac041. Van der Laan JW, Revision of ICH S8 needed?. Front. Toxicol. 4:866737. doi:10.3389/ftox.2022.866737

#### Projects

1. Dependence on benzodiazepines in rats. Behavioural and neurochemical research. 2. Carcinogenicity of human medicines. Building a database 1980\_1995. 3. Drugs and Autoimmunity. Effects of statines on rheumatoid arthritis model. 4. Carcinogenicity of growth factors. In vitro and in vivo studies with human insulin and its analogues 5. Comparison of embryotoxicity in rats and rabbits. Building a database. 6. Immunotoxicity of morphine and methadone. 7. Pharmacology and Carcinogenicity. Building a database of human medicines 8. Adjuvanted Vaccines and Autoimmunity.

#### Memberships

1. Health and Environmental Institute, Washington. Member of eSTAR committee 2. IMI TransQST Member of the Ethics Advisory Board. 5. Member Scientific Advisory Board EU\_ToxRisk Horizon2020 project 6. Past Chair Safety Working Party CHMP Participation and organization on various workshops in the field of human medicines \_ Vaccine toxicology \_ Pregnancy Labelling \_ Testing Reproductive toxicity in vivo and in vitro \_ Carcinogenicity \_ Adjuvants and Autoimmunity

#### Other Relevant Information