



Curriculum Vitae

Personal information **Carolien Versantvoort**

Work experience

1. Employer: Medicines Evaluation Board
 - Start date: 042004
 - End date:
 - Position: Senior Clinical Assessor (Pharmacology)
 - Activities: Clinical pharmacology assessor of NCEs. Scientific expert for clinical pharmacology for scientific advices. Clinical pharmacology assessor generics.
 - Country: Netherlands
2. Employer: National Institute for Public Health and the Environment
 - Start date: 1999
 - End date: 2004
 - Position: Senior scientist and non_clinical pharmacokinetic assessor
 - Activities: Senior Scientist at Department Toxicology. Research in the field of bioavailability of toxicants and risk assessment. Development of in vitro models to evaluate in vivo exposure. Non-clinical pharmacokinetic assessor of human medicines (NCEs).
 - Country: Netherlands
3. Employer: TNO Food
 - Start date: 1996
 - End date: 1999
 - Position: Scientist
 - Activities: Research on absorption of food and toxicants. Development of in vitro (ex vivo) models to evaluate in vivo exposure to food components, pharmaceuticals and toxicants. Hands_on experience with in vitro and ex vivo absorption models e.g. Caco_2 cells, intestinal segments.
 - Country: Netherlands
4. Employer: University of Cambridge
 - Start date: 1994
 - End date: 1995
 - Position: Scientist (PhD)
 - Activities: Scientist at Medical Research Council, Clinical Oncology and Radiotherapeutics Unit. Research on cellular pharmacology and genetics in the field on multidrug resistance in oncology.
 - Country: United Kingdom
5. Employer: Free University of Amsterdam
 - Start date: 1989
 - End date: 1994
 - Position: PhD student
 - Activities: PhD student at Department Clinical research internal medicine and oncology, section cellular pharmacology. Research field cellular pharmacology of anticancer agents in multidrug resistant cancer cell lines.
 - Country: Netherlands

Education and training

1. Subject: Free University of Amsterdam
 - Start date: 1989
 - End date: 1994
 - Qualification: Dr in Internal Medicine and Oncology (Cellular Pharmacology)
 - Organisation: Research field cellular pharmacology of anticancer agents in multidrug resistant cancer cell lines.
 - Country: Netherlands
2. Subject: University of Utrecht
 - Start date: 1984
 - End date: 1989
 - Qualification: Master in Chemistry
 - Organisation: Master in Chemistry with major in Biochemistry
 - Country: Netherlands

Additional information

Publications

Yang X, Versantvoort C, Hoshino M, Ishiguro A, (2026), Advances and Challenges for Drug Interaction Evaluation - Perspectives on the ICH M12 Guideline. *Drug Metabolism and Pharmacokinetics*, <https://doi.org/10.1016/j.dmpk.2026.101527>.

Reynolds, K., Yang, X., Peters, S. A., Sinha, V., Heymann, H., Borges, L. N., ... & Madabushi, R. (2025). ICH M12 Drug Interaction Studies: Summary of the Efforts to Achieve Global Convergence. *Clinical Pharmacology & Therapeutics*.

Simons, C. W., Maton, L. C., van Dartel, M., van den Heuvel, M., den Otter, L., Versantvoort, C., ... & Koomen, J. V. (2025). A review on the role of extrapolation as basis for paediatric marketing authorization applications of medicines in the EU. *British Journal of Clinical Pharmacology*.

Paul, P., Colin, P. J., Musuamba Tshinanu, F., Versantvoort, C., Manolis, E., & Blake, K. (2025). Current Use of Physiologically Based Pharmacokinetic modeling in New Medicinal Product Approvals at EMA. *Clinical Pharmacology & Therapeutics*, 117(3), 808-817.

Efthymios Manolis, Alfredo García-Arieta, Anders Lindahl, Evangelos Kotzagiorgis, Jobst Limberg, Øyvind Holte, Paulo Paixao, Carolien Versantvoort, Flora Musuamba Tshinanu, Kevin Blake, Michiel Van Den Heuvel Using mechanistic models to support development of complex generic drug products: European Medicines Agency perspective. *CPT Pharmacometrics Syst Pharmacol*. 2023 Jan 11.

Marieke JHJ Dekker, Sieta T de Vries, Carolien HM Versantvoort, Ellen GE Drost_van Velze, Mansi Bhatt, Peter JK van Meer, Ineke K Havinga, Christine C Gispen_de Wied, Peter GM Mol, Sex proportionality in pre_clinical and clinical trials: an evaluation of 22 marketing authorization application dossiers submitted to the European Medicines Agency, *Frontiers in Medicine*, 2021

Luzon E, Blake K, Cole S, Nordmark A, Versantvoort C, Gil Berglund E Physiologically_Based Pharmacokinetic modelling in regulatory decision making at the European Medicines Agency; *Clinical Pharmacology & Therapeutics* 2016

Versantvoort C, Maliepaard M, Lekkerkerker F. Generics: what is the role of Registration Authorities. *The Netherlands Journal of Medicine*; 66(2): 62_66, 2008

E.F. Brandon, A.O. Oomen, C.J.M. Rompelberg, C.H.M. Versantvoort, J.G. van Engelen, A.J.A.M. Sips Consumer product in vitro digestion model: Bioaccessibility of contaminants and its application in risk assessment. *Regul Toxicol Pharmacol.*;44(2):161_71. 2006

C.H.M. Versantvoort, A.O. Oomen E.van de Kamp, C.J.M. Rompelberg, A.J.A.M Sips Applicability of an in vitro digestion model in assessing the bioaccessibility of mycotoxins from food. *Food and Chemical Toxicology*, 43: 31_40, 2005

LL de Zwart, HE Haenen, CHM Versantvoort, G Woltering, J.G. van Engelen, A.J.A.M. Sips Role of biokinetics in risk assessment of drugs and chemicals in children. *Regul Toxicol Pharmacol*. 39(3):282_309, 2004

C.H.M. Versantvoort, R.C.A. Onderwater, E. Duizer, J.J.M. van de Sandt, A.J. Gilde, J.P. Groten Monolayers of IEC_18 cells as an in vitro model for screening the passive transcellular and paracellular transport across the intestinal barrier: comparison of active and passive transport with the human colon carcinoma Caco_2 cell line. *Environ Toxicol Pharmacol* 2002; 11:335_44

J.D. van der Klis, C.H.M. Versantvoort The relationship between intestinal morphology and absorptive capacity in broilers. 2000

E. Duizer, A.J. Gilde, C.H.M. Versantvoort, J.P. Groten Effects of cadmium chloride on the paracellular barrier function of intestinal epithelial cell lines. *Tox. Appl. Pharmacol.*, 155, 117_126, 1999

E. Duizer, C. Van der Wulp, C.H.M. Versantvoort, J.P. Groten Absorption enhancement, structural changes in tight junctions and cytotoxicity caused by palmitoyl carnitine in Caco_2 and IEC_18 cells. *J. Pharmacol. Exp. Ther.*, 287: 395_402, 1998

C.H.M. Versantvoort, W.R. Leeman, E. Duizer, and J.P. Groten Characterisation of drug transport in cell lines and isolated intestinal segments by using a small_scale transport device. *Eur. J. Pharm. Sci.*, 5: S56, 1997

R. Gonzalez Manzano, C. Versantvoort, K. Wright, P.R. Twentyman Rapid recovery of a functional MDR phenotype caused by MRP after a transient exposure to MDR drugs in a revertant human lung cancer cell line. *Eur.J. Cancer*, 32A: 2136_2141, 1996

P.R. Twentyman, C.H.M. Versantvoort Experimental modulation of MRP (multidrug resistance_associated protein)_mediated resistance. *Eur.J. of Cancer*, 32A: 1002_1009, 1996

C.H.M. Versantvoort, T. Rhodes, P.R. Twentyman Acceleration of MRP_associated efflux of rhodamine 123 by genistein and related compounds. *Br. J. of Cancer*, 74: 1949_1954, 1996

C.H.M. Versantvoort, H.J. Broxterman, T. Bagrij, R.J. Scheper, P.R. Twentyman Regulation by glutathione of drug transport in multidrug resistant human lung tumour cell lines overexpressing MRP. *British Journal of Cancer*, 72: 82_89 1995

C.H.M. Versantvoort, T. Bagrij, K.A. Wright, P.R. Twentyman On the relationship between the probenecid_sensitive transport of daunorubicin or calcein and glutathione kinetics in cells overexpressing the multidrug resistance_associated protein (MRP). *Int.J.Cancer*, 63: 855_862, 1995

H.J. Broxterman, C.H.M. Versantvoort The pharmacology of drug transport in multidrug resistant tumor cells. in *Alternative Mechanisms of Multidrug Resistance in Cancer*. J.A. Kellen (Ed), Birkhäuser Publ., Boston, pp 67_81, 1995

H.J. Broxterman, N. Feller, C.M. Kuiper, C.H.M. Versantvoort, T. Teerlink, H.M. Pinedo, J. Lankelma Correlation between functional and molecular analysis of MDR_1/P_glycoprotein in human solid tumor xenografts. *International Journal of Cancer*, 61: 880_886, 1995

E.W.H.M. Eijndems, G.J.R. Zaman, M. de Haas, C.H.M. Versantvoort, M.J. Flens, R.J. Scheper, E. Kamst, P. Borst, F. Baas Altered MRP is associated with multidrug resistance and reduced drug accumulation in human SW_1573 cells. *British Journal of Cancer*, 72: 298_306, 1995

C.H.M. Versantvoort, S. Withoff, H.J. Broxterman, N.H. Mulder, C.M. Kuiper, R.J. Scheper, E.G.E. de Vries Resistance associated factors in human small cell lung carcinoma GLC4 sublines with increasing adriamycin resistance. *International Journal of Cancer*, 61: 375_380, 1995

H.J. Broxterman, C.H.M. Versantvoort, S.C. Linn Multidrug resistance in lung cancer in *Lung Cancer _ Biological and Clinical Aspects*. Heine H. Hansen (Ed.), Kluwer Academic Publ., Norwell USA, pp. 193_222, 1994

C.H.M. Versantvoort, H.J. Broxterman, J. Lankelma, N. Feller, H.M. Pinedo Competitive inhibition by genistein and ATP dependence of daunorubicin transport in intact MRP overexpressing human small cell lung cancer cells. *Biochemical Pharmacology*, 48: 1129_1136, 1994

C.H.M. Versantvoort, G.J. Schuurhuis, H.M. Pinedo, C.A. Eekman, C.M. Kuiper, J. Lankelma, H.J. Broxterman Genistein modulates the decreased drug accumulation in non_P_glycoprotein mediated multidrug resistant tumor cells. *British Journal of Cancer*, 68: 939_946, 1993

G.J.R. Zaman, C.H.M. Versantvoort, J.J.M. Smit, E.W.H.M. Eijndems, M. de Haas, A.J. Smith, H.J. Broxterman, N.H. Mulder, E.G.E. de Vries, F. Baas, P. Borst Analysis of the expression of MRP, the gene for a new putative transmembrane drug transporter, in human multidrug resistant lung cancer cell lines. *Cancer Research*, 53: 1747_1750, 1993

E.W.H.M. Eijndems, P. Borst, A.P.M. Jongsma, S. de Jong, E.G.E. de Vries, M. van Groenigen, C.H.M. Versantvoort, A.W.M. Nieuwint, F. Baas Genetic transfer of non_P_glycoprotein_mediated multidrug resistance (MDR) in somatic cn colon carcinoma caco_2 cell line. *Environmental Toxicology and Pharmacology*, 11: 335_344, 2002 ell fusion:

Dissection of a compound MDR phenotype. Proceedings National Academy of Science USA, 89: 3498_3502, 1992

C.H.M. Versantvoort, H.J. Broxterman, N. Feller, H. Dekker, C.M. Kuiper, J.Lankelma Probing daunorubicin accumulation defects in non_P_glycoprotein expressing multidrug-resistant cell lines using digitonin. International Journal of Cancer, 50: 906_911, 1992

C.H.M. Versantvoort, H.J. Broxterman, H.M. Pinedo, N. Feller, C.M. Kuiper, J.Lankelma Energy-dependent processes involved in reduced drug accumulation in multidrug-resistant human lung cancer cell lines without P_glycoprotein expression. Cancer Research, 52: 17_23, 1992

D. Hardeman, C. Versantvoort, J.M. van den Brink, H. van den Bosch Studies on peroxisomal membranes. Biochim. Biophys. Acta, 1027: 149_154, 1990

Reports available from <<http://www.rivm.nl/en/>>, national Institute for Public Health and the Environment, Bilthoven, The Netherlands RIVM report 630030_001 (2000) Methodologies to study human intestinal absorption. A review. C.H.M. Versantvoort, C.J.M. Rompelberg, A.J.A.M. Sips

Briefrapport (2001) Haalbaarheidsstudie naar validatie van het in vitro digestiemodel. C.H.M. Versantvoort, C.J.M. Rompelberg RIVM Report 623860011 (2002)

Pharmacokinetics of ingested xenobiotics in children: A comparison with adults LL de Zwart, HEMG Haenen, CHM Versantvoort, AJAM Sips Briefrapport (2003) Het bepalen van orale biobeschikbaarheid met behulp van in vitro methodieken. Haalbaarheidsstudie naar koppeling van het in vitro digestiemodel met het in vitro Caco_2 darmtransportmodel. C.H.M. Versantvoort RIVM report 320102_001 (2003)

Development and suitability of in vitro digestion models in assessing bioaccessibility of lead from toy matrices. AG Oomen, K van Twillert, CJM Rompelberg, CHM Versantvoort RIVM report 320102_002 (2004) Development of an in vitro digestion model to determine the bioaccessibility of contaminants from food. Report No. 320102002, CHM Versantvoort, E van de Kamp, CJM Rompelberg

Report No. 320102003 (2004) Application of in vitro digestion models to assess release of lead and phthalate from toy matrices and azo dyes from textile. Oomen, A.G., Versantvoort, C.H.M., Duits, M.R., Van de Kamp, E., Van Twillert, K., 2004. Report No. 320102003. available from <<http://www.rivm.nl/en/>>, national Institute for Public Health and the Environment, Bilthoven, The Netherlands

Report No. 320102004 (2005) Consumer product in vitro digestion model: bioaccessibility of contaminants from toys and application in risk assessment. Oomen, A.G., Rompelberg, C.J.M., Brandon, E.F.A., Van de Kamp, E., Duits, M.R., Versantvoort, C.H.M., van Engelen, J.G.M., Sips, A.J.A.M

Projects

Memberships

2024_ member of leaderships team of Special Interest Area Clinical Pharmacology

2023_.... Chair of Clinical Pharmacology Operational expert group

2014_2022 member of the Pharmacokinetic Working Party at EMA (2020_2022 as Chair)

2018_2024 ICH Expert on harmonisation of drug drug interaction guideline (ICH_M12)

Other Relevant Information