

**PERSONAL INFORMATION** **Sabine Straus****WORK EXPERIENCE**

July 2012–Present **staff member**  
MEB (Netherlands)  
PRAC member

December 2005–June 2012 **head of PhV**  
MEB (Netherlands)

2010–Present **associate professor**  
Erasmus MC (Netherlands)

2001–2005 **senior assessor pharmacovigilance**  
MEB (Netherlands)

**EDUCATION AND TRAINING**

September 1978–1985 **MD**  
university Utrecht (Netherlands)

2002–2003 **MSc in Epidemiology**  
erasmus university (Netherlands)

2001–2005 **PhD**  
erasmus university (Netherlands)

**ADDITIONAL INFORMATION**

**Expertise** signal detection /signal management  
pharmaco epidemiology  
(additional) risk minimisation, pregnancy prevention programs and assessment of effectiveness  
risk communication

**Publications** Mazzaglia G, Straus SMJ, Arlett P, da Silva D, Janssen H, Raine J, Alteri E.  
Study Design and Evaluation of Risk Minimization Measures: A Review of Studies Submitted to the European Medicines Agency for Cardiovascular, Endocrinology, and Metabolic Drugs.  
Drug Saf. 2018 Feb;41(2):191-202  
Pacurariu AC, Coloma PM, Gross-Martirosyan L, Sturkenboom MC, Straus SM.  
Decision making in drug safety-a literature review of criteria used to prioritize newly detected safety issues.  
Pharmacoepidemiol Drug Saf. 2017 Mar;26(3):327-334  
Gadroen K, Kemmeren JM, Bruijning-Verhagen PC, Straus SM, Weibel D, de Melker HE, Sturkenboom MC.  
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de Bie S, Kaguelidou F, Verhamme KM, De Ridder M, Picelli G, Straus SM, Giaquinto C, Stricker BH, Bielicki J, Sharland M, Sturkenboom MC; ARPEC study Using Prescription Patterns in Primary Care to Derive New Quality Indicators for Childhood Community Antibiotic Prescribing.

Pediatr Infect Dis J. 2016 Dec;35(12):1317-1323

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Vermeer NS, Straus SM, Mantel-Teeuwisse AK, Hidalgo-Simon A, Egberts AC, Leufkens HG, De Bruin ML.

Drug-induced progressive multifocal leukoencephalopathy: Lessons learned from contrasting natalizumab and rituximab.

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Segec A, Keller-Stanislawski B, Vermeer NS, Macchiarulo C, Straus SM, Hidalgo-Simon A, De Bruin ML.

Strategy in Regulatory Decision-Making for Management of Progressive Multifocal Leukoencephalopathy.

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de Bie S, Ferrajolo C, Straus SM, Verhamme KM, Bonhoeffer J, Wong IC, Sturkenboom MC; GRiP network.

Pediatric Drug Safety Surveillance in FDA-AERS: A Description of Adverse Events from GRiP Project.

PLoS One. 2015 Jun 19;10(6):

de Bie S, Coloma PM, Ferrajolo C, Verhamme KM, Trifirò G, Schuemie MJ, Straus SM, Gini R, Herings R, Mazzaglia G, Picelli G, Ghirardi A, Pedersen L, Stricker BH, van der Lei J, Sturkenboom MC; EU-ADR consortium.

The role of electronic healthcare record databases in paediatric drug safety surveillance: a retrospective cohort study.

Br J Clin Pharmacol. 2015 Aug;80(2):304-14

Patadia VK, Schuemie MJ, Coloma P, Herings R, van der Lei J, Straus S, Sturkenboom M, Trifirò G.

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Br J Clin Pharmacol. 2015 Feb 16. [Epub ahead of print]

Niels S Vermeer, Irina Spierings, Aukje K Mantel-Teeuwisse, Sabine MJM Straus, Thijs J Giezen, Hubert GM Leufkens, Toine CG Egberts, and Marie L De Bruin

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Peter G. M. Mol, Ama H. Arnardottir, Domenico Motola, Patrick J. Vrijlandt, Ruben G. Duijnhoven, Flora M. Haaijer-Ruskamp, Pieter A. de Graeff, Petra Denig, Sabine M. J. M. Straus

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Inge M. Zomerdijk, Gianluca Trifirò, Fakhredin A. Sayed-Tabatabaei, Miriam C. J. M. Sturkenboom and Sabine M. J. M. Straus

Measuring the effect of risk minimization measures – can existing healthcare databases be used?

Pharmacoepidemiol Drug Saf. 2013;22(10):1046-53.

Niels S. Vermeer, Sabine M. J. M. Straus , Aukje K. Mantel-Teeuwisse,

Francois Domergue, Toine C. G. Egberts ,Hubert G. M. Leufkens,

Marie L. De Bruin

Traceability of Biopharmaceuticals in Spontaneous Reporting Systems: A Cross-Sectional Study in the FDA Adverse Event Reporting System (FAERS) and EudraVigilance Databases

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Van Blijderveen JC, Verhamme KM, Zietse R, Visser LE, Romio SA, Buhre PN, Sturkenboom MC, Hofman A, Straus SM, Stricker BH

Overanticoagulation is associated with renal function decline.

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Eur J Haematol. 2012; 89(3):256-66.

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Rikje Ruiten, Loes E. Visser, Myrthe P.P. van Herk-Sukel, Petronella H. Geelhoed- Duijvestijn, Sandra de Bie, Sabine M.J.M. Straus, Peter G.M. Mol, Silvana A. Romio, Ron M.C. Herings and Bruno H.Ch. Stricker

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Crijns HJ, van Rein N, Gispén-de Wied CC, Straus SM, de Jong-van den Berg LT.

Prescriptive contraceptive use among isotretinoin users in the Netherlands in comparison with non-users: a drug utilisation study.

Pharmacoepidemiol Drug Saf. 2012

Crijns, Ineke; Straus, Sabine; Luteijn, Michiel; Gispén-de Wied, Christine; Raine, June; de Jong-van den Berg, Lolkje

Implementation of the Harmonized EU Isotretinoin Pregnancy Prevention Programme: A Questionnaire Survey among European Regulatory Agencies

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Ruiten R, Visser LE, van Herk-Sukel MP, Coebergh JW, Haak HR, Geelhoed-Duijvestijn PH, Straus SM, Herings RM, Stricker BH.

Lower risk of cancer in patients on metformin in comparison with those on sulfonylurea derivatives: results from a large population-based follow-up study.

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Arna H. Arnardottir, Flora M. Haaijer-Ruskamp, Sabine M.J. Straus, Pieter A. de Graeff, Peter G.M. Mol

Effect of Safety Issues with HIV Drugs on the Approval Process of Other Drugs in the Same Class: An Analysis of European Public Assessment Reports.

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Ruiten R, Visser LE, van Herk-Sukel MP, Coebergh JW, Haak HR, Geelhoed-Duijvestijn PH, Straus SM, Herings RM, Stricker BH.

Risk of cancer in patients on insulin glargine and other insulin analogues in comparison with those on human insulin: results from a large population-based follow-up study.

Diabetologia. 2012 Jan;55(1):51-62. Epub 2011

14Crijns HJ, Jentink J, Game E, Gispén-de Wied CC, Straus SM, de Jong-van den Berg LT; for the EUROCAT Working Group.

The Distribution of Congenital Anomalies Within the VACTERL Association Among Tumor Necrosis Factor Antagonist-exposed Pregnancies Is Similar to the General Population.

J Rheumatol. 2011;38(9):1871-1874

Härmark L, van Puijenbroek E, Straus S, van Grootheest K.

Intensive monitoring of pregabalin: results from an observational, Web-based, prospective cohort study in the Netherlands using patients as a source of information.

Drug Saf. 2011;34(3):221-31

Teichert M, Visser LE, Uitterlinden AG, Hofman A, Buhre PJ, Straus S, De Smet PA, Stricker BH.

Selective serotonin reuptake inhibiting antidepressants and the risk of overanticoagulation during acenocoumarol maintenance treatment.

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Additional safety risk to exceptionally approved drugs in Europe?

Br J Clin Pharmacol. 2011;72(3):490-9

Willemsen MJ, Mantel-Teeuwisse AK, Straus SM, Meyboom RH, Egberts TC Leufkens HG.

Use of dipeptidyl peptidase-4 inhibitors and the reporting of infections: a disproportionality analysis in the World Health Organization Vigibase.

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H.J.M.J. Crijns, S.M. Straus, C.h. Gispen-de Wied, L.T.W De Jong-van den Berg : Compliance with Pregnancy Prevention Programs of isotretinoin in Europe: a systematic review

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Proton pump inhibitors and the risk of overanticoagulation during acenocoumarol maintenance treatment.

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van Noord C, Sturkenboom MC, Straus SM, Witteman JC, Stricker BH.

Non-cardiovascular drugs that inhibit hERG-encoded potassium channels and risk of sudden cardiac death.

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Thijs J, Giezen, Aukje K, Mantel-Teeuwisse, Ronald H.B, Meyboom, Sabine M.J.M. Straus, Hubert G.M. Leufkens, and Toine C.G. Egberts

Mapping the Safety Profile of Biologicals.

A Disproportionality Analysis Using the WHO Adverse Drug Reaction Database, Vigibase

Drug Saf;2010;3:865-878

Peter G.M. Mol, Sabine M.J.M. Straus, Sigrid Piening, Jonie T.N. de Vries, Pieter A. de Graeff and Flora M. Haaijer-Ruskamp

A Decade of Safety-related Regulatory Action in the Netherlands. A Retrospective Analysis of Direct Healthcare Professional Communications issued by Pharmaceutical Companies in Collaboration with the Dutch Medicines Evaluation Board and European Medicines Agency (EMA) from 1999 to 2009.

Drug Saf 2010;33:463-74

Martina Teichert, Loes E Visser, Mark Dufour, Eline Rodenburg, Sabine MJM Straus, Peter AGM De Smet, Bruno HCh Stricker

Isotretinoin use and compliance with the Dutch pregnancy prevention program: a retrospective cohort study in Dutch females of reproductive age with pharmacy dispensing data.

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Eur J Endocrinol 2010;162:241-248

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BH.

The association of serum testosterone levels and ventricular repolarization

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Thijs J. Giezen, Aukje K. Mantel-Teeuwisse, Sabine M.J.M. Straus, Antoine C.G. Egberts, Stella Blackburn, Ingemar Persson, Hubert G.M. Leufkens.

Evaluation of Post-Authorisation Safety Studies in the first cohort of EU Risk Management Plans at time of regulatory approval: Where are we?"

Drug Saf 2009; 32 (12): 1175-1187

Charlotte van Noord, MD, Miriam C.J.M. Sturkenboom, PharmD, PhD, Sabine M.J.M. Straus MD, PhD, Albert Hofman, MD, PhD, Jacqueline C.M. Witteman, PhD, Bruno H. Ch. Stricker, MMed, PhD

Population-based studies of antithyroid drugs and sudden cardiac death

Br J Clin Pharmacol 2009;68 (3): 447-454

Thijs J. Giezen, Sabine M.J.M. Straus, Aukje K. Mantel-Teeuwisse

Pharmacovigilance of biosimilars from a regulatory point of view: Is there a need for a specific approach?

International Journal of Risk & Safety in Medicine 2009 (21) 53-58

Willemens MJ, Mantel-Teeuwisse AK, Straus SM, Leufkens HG, Egberts AC, Sturkenboom MC.

Cardiovascular and psychiatric risk profile and patterns of use in patients starting anti-obesity drugs.

Pharmacoevidemiol Drug Saf. 2009;18(7):631-8

Charlotte van Noord, Albert-Jan L.H.J. Aarnoudse, Mark Eijgelsheim,

Miriam C.J.M. Sturkenboom, Sabine M.J.M. Straus, Albert Hofman, Jan A. Kors, Christopher Newton-Cheh, Jacqueline C.M. Witteman, Bruno H.Ch. Stricker, Calcium channel blockers, NOS1AP and QTc prolongation. Pharmacogenetics and Genomics, 2009;19(4):260-6

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J Clin Psychopharmacol. 2009 ; 29(1):9-15

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Egberts AC

Psychiatric and cardiovascular comorbidities in patients with diabetes mellitus starting antiobesity drugs.

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Common NOS1AP variants are associated with a prolonged QTc interval in the Rotterdam Study. Circulation. 2007;116(1):10-6

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Bleumink GS, Knetsch AM, Sturkenboom MC, Straus SM, Hofman A, Deckers JW, Witteman JC, Stricker BH.

Quantifying the heart failure epidemic: prevalence, incidence rate, lifetime risk and prognosis of heart failure. The Rotterdam Study.

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Antipsychotics and the risk of sudden cardiac death.

Arch Intern Med. 2004;164(12):1293-7.

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Incidence of sudden cardiac death in the general population.

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Nederlandse publicaties

C. van Noord, .S M.J.M. Straus, R van Mechelen, J.M. Akkerhuis, M. C.J.M. Sturkenboom, B. H. Ch. Stricker.

QTc-verlenging bij electrocardiografie en medicatie in de praktijk.

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Swaan CM, van der Sande MA, Speelman P, Conyn-van Spaendonck MA, Straus SM, Coutinho RA. Bijwerkingen van influenza vaccinatie [Adverse events following influenza vaccination: reaction to specific reports and the necessity of a central registration system]

Ned Tijdschr Geneesk. 2007;151(39):2166-9..

Straus S.M.J.M., Lekkerkerker J.F.F.

Kennis zonder bijwerkingen

Medisch Contact 2004;37:144-1446

Voordouw ACG, Straus SMJM. Kunnen er weer griepachtige verschijnselen ontstaan na een 2e vaccinatie tegen hepatitis B? [What is known about the recurrence of flu-like symptoms following a second vaccination against hepatitis B?]

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van Grootheest AC, Straus SMJM, Heeringa M.

Bijwerkingen van Sildenafil, 2 jaar praktijkervaring [Side effects of sildenafil: findings from two years practical experience]

Ned Tijdschr Geneesk. 2001 ;145(11):526-9.

Straus S, Nab HW, Meiners AP, Broekmans AW

Post-marketing surveillance: wetenschappelijk onderzoek of promotie van geneesmiddelen.

Huisarts en wetenschap 1999 ; 42: 505-08

SMJM Nierop-Straus  
Acupunctuur en verslaving.  
Acupunctur 1989;13:14-24  
WMA Verhoeven en S. Straus  
Neuropeptiden en depressie  
Tijdschrift voor psychiatrie 1986 (9):622-32

**Projects** nvolvement in supervision of academic research/PhD research , covering (additional) risk minimisation measures, risk communication, methodology in signal detection, renal ADR and biologicals.  
advisory role in  
SAFEGUARD (The European project SAFEGUARD aims to assess and further quantify and understand the cardio/cerebrovascular and pancreatic safety of blood glucose lowering agents, in particular the thiazolidinedones (TZDs) and the novel incretin-based drugs and amylin analogues in Type 2 Diabetes Mellitus (T2DM) patients)  
ARITMO (the European project ARITMO aims to analyse the arrhythmic potential of drugs in the following classes of study drugs (> 250 compounds): antipsychotics, anti-infectives (antibacterials, antimycotics and antivirals ) and H1-antihistamines, globally and in specific subgroups (age, co-morbidity, genetically).

**Memberships** ISPE

**Other Relevant Information**