

JUHAERI JUHAERI, Ph. D.

VP & Head, Global Safety Sciences, Sanofi
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SUMMARY

Juhaeri Juhaeri Ph.D. is Vice President and Head of Global Safety Sciences at Sanofi with an extensive experience in the leadership and management of diverse teams in Sanofi and in various public-private initiatives in collaboration with regulatory agencies, academia and pharmaceutical industry. He is leading a team of 90 experts responsible for the development, coordination, and implementation of the strategy to incorporate state-of-the-art Safety Sciences (Pharmacoepidemiology, Data Mining, Signal Detection, Risk Management, Benefit Risk Evaluation and Pharmacovigilance Sciences) for Sanofi investigational and over 1300+ post-marketing products.

An epidemiologist and statistician, Juhaeri has more than 20 year experience in Epidemiology, Biostatistics, Signal Detection, Risk Management and Quantitative Benefit-Risk evaluation. He joined Sanofi in early 2001 where he helped establish a system for epidemiologic research utilizing existing databases (one of the first in the industry) and a system for data mining and signal detection using various data sources. As a leader and a scientific contributor, Juhaeri has been actively involved in various external collaborative projects in Pharmacoepidemiology, Quantitative Benefit-Risk (BR) Evaluation, Signal Detection and Risk Management. He is a member of the Scientific Advisory Committee of Innovation in Medical Evidence Development and Surveillance (IMEDS), a program under The Reagan-Udall, an independent 501(c)(3) not-for-profit organization created by Congress to advance regulatory science needed by the Food and Drug Administration (FDA) to accomplish its mission. He is also the Steering Committee member and the Industry Lead of PREFER (Patient Preferences in Benefit-Risk Assessments during the Drug Life Cycle), a five year European public-private research project where academic researchers and the pharmaceutical industry work together to find out when and where patients want, can and should be involved in drug development. He was a member of the Steering Committee of the Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium (PROTECT), another collaborative European project to address limitations of current methods in the field of pharmacoepidemiology and pharmacovigilance coordinated by the European Medicine Agency. He has also been active in various external collaborative projects in Asia and US, including PhRMA OMOP, and has successfully evaluated and applied OMOP as well as FDA Sentinel methods in Sanofi.

Juhaeri is also recognized as a leading expert in Pharmacoepidemiology and has been invited to speak in numerous scientific meetings. In the last year, he had delivered over a dozen lectures and speeches on Pharmacoepidemiology, Quantitative Benefit-Risk Evaluation, Signal Detection and Risk Management in the DIA, ISPE and ISOP and other international meetings in the US, Europe and Asia. He has also been invited by Shanghai ADR and Chinese National ADR to provide trainings on these fields. He has published extensively with over 90 peer-reviewed publications and abstracts.

Juhaeri is an Adjunct Faculty at the Gillings School of Global Public Health, University of North Carolina Chapel Hill, North Carolina. He received his Ph.D. in Epidemiology from the same university.

EDUCATION

EPIDEMIOLOGY

1999 **Doctor of Philosophy (PhD)**
Department of Epidemiology
School of Public Health
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina

Dissertation: "Weight Change, Dieting, and Hypertension: Atherosclerosis Risk in Communities (ARIC) Study"

1996 **Master of Science (MS)**
Department of Public Health Sciences
Wake Forest University School of Medicine
Winston-Salem, North Carolina

Thesis: "Correlates of Co-morbidities among End-Stage Renal Disease Patient: Kidney Outcomes Prediction and Evaluation (KOPE) Study"

STATISTICS

1990 **Sarjana, Cum Laude**
Department of Statistics
Bogor Agricultural University
Bogor, Indonesia

Thesis: "Decomposition of Multi-normal Distribution using Maximum Likelihood Method"

PROFESSIONAL EXPERIENCE

September 2015 – present

Vice President and Head, Global Safety Sciences

- Lead, manage and mentor team of 90 experts in the US, Europe and Asia: Professional and career development, state-of-the-art epidemiology and signal detection methodologies and practices, post-marketing and investigational Pharmacoepidemiology and safety monitoring/data analysis techniques, regulatory guidelines (ICH, CIOMS, FDA, EU) regarding patient confidentiality, patient registries, Pharmacoepidemiology data sources and study guidelines,
- Lead the development, coordination, and implementation of the strategy to incorporate state-of-the-art Safety Sciences (Pharmacoepidemiology, Data Mining, Signal Detection, Risk Management, Benefit Risk Evaluation and Pharmacovigilance Sciences) for Sanofi investigational and over 1300+ post-marketing products

April – September 2015

**Vice President and Head, Pharmacoepidemiology and Signal Detection
Sanofi**

- Lead, manage and mentor team personnel (11 direct reports): Professional and career development, state-of-the-art epidemiology and signal detection methodologies and practices, post-marketing and investigational Pharmacoepidemiology and safety monitoring/data analysis techniques, regulatory guidelines (ICH, CIOMS, FDA, EU) regarding patient confidentiality, patient registries, Pharmacoepidemiology data sources and study guidelines,
- Lead the development, coordination, and implementation of the strategy to incorporate state-of-the-art epidemiology practices in all Pharmacoepidemiology studies and Signal Detection for Sanofi investigational and post-marketing products (1300+),
- Lead transversal interactions and collaborations with other departments within Sanofi, especially Pharmacovigilance, Medical Affairs, Regulatory Affairs, Pre-clinical and Clinical Development, Marketing and others and serve as lead consultant to provide Pharmacoepidemiology expertise to other groups within the company,
- Given limited man power and large number of products, ensure the application of the most effective approaches to performing pharmacoepidemiologic studies and signal detection activities (usually a maximum of 3 months when using existing databases),
- Lead Pharmacoepidemiology projects as part of Risk Management Activities, including but not limited to development of RMP documents, design and implementation of Post-Approval Safety Studies (PASS) or Post-Approval Efficacy Studies (PAES), studies to evaluate the effectiveness of Risk Minimization measures (such as Drug Utilization Studies and Prescription Surveys), responses to authorities,
- Lead the development and implementation of a strategy and process for acquisition, rapid access and analysis of data sources capable of providing critical background incidence and prevalence data, patterns of drug utilization, independent risk factors for specific adverse events, etc., to facilitate analysis and interpretation of critical product safety issues,
- Lead the development and implementation of quantitative Benefit-Risk (BR) approaches to evaluating benefit-risk profiles of Sanofi drugs. Since quantitative BR methods are new and relatively unknown, lead the communication and discussions with upper management to convince them the benefit of using the methods early in the development of drugs,

- Lead the development and the Governance and Processes of the BR Evaluations of Sanofi Products,
- Serve as a core member in the Sanofi Safety Management Committee to review all safety issues, provide Pharmacoepidemiology input and provide final decision on the status of the issue,
- Be responsible for and lead the communication, presentations, and discussions of Pharmacoepidemiology-related issues with Regulatory Authorities around the world,
- Lead external scientific collaborations with regulatory agencies, other pharmaceutical companies and academia in the US, Europe and Asia: for example, IMI-PROTECT (European consortium for pharmacoepidemiology research), PhRMA OMOP (Observational Medical Outcome Partnership), IMEDS (Innovation in Medical Evidence Development and Surveillance), collaboration with Shanghai ADR and Chinese ADR,
- Lead contribution to scientific community via leadership in various public-private partnerships, presentations in various regulatory and scientific forums, and publications in peer-reviewed journals,
- Manage Pharmacoepidemiology and Signal Detection department budget.

Sept 2012 to April 2015

Associate Vice President and Head, Pharmacoepidemiology Sanofi

- Lead, manage and mentor team personnel (14 direct reports): Professional and career development, state-of-the-art epidemiology methodologies and practices, post-marketing and investigational Pharmacoepidemiology and safety monitoring/data analysis techniques, regulatory guidelines (ICH, CIOMS, FDA, EU) regarding patient confidentiality, patient registries, Pharmacoepidemiology data sources and study guidelines,
- Lead the development, coordination, and implementation of the strategy to incorporate state-of-the-art epidemiology practices in all Pharmacoepidemiology studies for Sanofi investigational and post-marketing products (1300+),
- Lead transversal interactions and collaborations with other departments within Sanofi, especially Pharmacovigilance, Medical Affairs, Regulatory Affairs, Pre-clinical and Clinical Development, Marketing and others and serve as lead consultant to provide Pharmacoepidemiology expertise to other groups within the company,
- Lead the development and implementation of Observational Study Governance and Processes in Sanofi, especially for studies using pre-existing databases (a total of 8 QDs) and lead the maintenance for audit and for inspection readiness. Ensure synergy between Pharmacoepidemiology and Sanofi Processes,
- Given limited man power and large number of products, ensure the application of the most effective approaches to performing pharmacoepidemiologic studies (usually a maximum of 3 months when using existing databases),
- Lead Pharmacoepidemiology projects as part of Risk Management Activities, including but not limited to development of RMP documents, design and implementation of Post-Approval Safety Studies (PASS) or Post-Approval Efficacy Studies (PAES), studies to evaluate the effectiveness of Risk Minimization measures (such as Drug Utilization Studies and Prescription Surveys), responses to authorities,
- Lead the development and implementation of a strategy and process for acquisition, rapid access and analysis of data sources capable of providing critical background incidence and

prevalence data, patterns of drug utilization, independent risk factors for specific adverse events, etc., to facilitate analysis and interpretation of critical product safety issues,

- Lead the development and implementation of quantitative Benefit-Risk (BR) approaches to evaluating benefit-risk profiles of Sanofi drugs. Since quantitative BR methods are new and relatively unknown, lead the communication and discussions with upper management to convince them the benefit of using the methods early in the development of drugs,
- Lead the development and the Governance and Processes of the BR Evaluations of Sanofi Products,
- Serve as a core member in the Sanofi Safety Management Committee to review all safety issues, provide Pharmacoepidemiology input and provide final decision on the status of the issue,
- Be responsible for and lead the communication, presentations, and discussions of Pharmacoepidemiology-related issues with Regulatory Authorities around the world,
- Lead external scientific collaborations with regulatory agencies, other pharmaceutical companies and academia in the US, Europe and Asia: for example, IMI-PROTECT (European consortium for pharmacoepidemiology research), PhRMA OMOP (Observational Medical Outcome Partnership), IMEDS (Innovation in Medical Evidence Development and Surveillance), collaboration with Shanghai ADR and Chinese ADR,
- Lead contribution to scientific community via leadership in various public-private partnerships, presentations in various regulatory and scientific forums, and publications in peer-reviewed journals,
- Manage Pharmacoepidemiology budget.

May 2010 – Sep 2011

Head, Signal Detection and Management (dual role, in addition to Epidemiology position), Sanofi

- Build a new team responsible for data mining, quantitative signal detection and management of all Sanofi products,
- Build pro-active signal detection and evaluation system - design, conduct and analysis: oversight, coordination, and scientific guidance for pro-active signal management activities utilizing spontaneous reporting systems, including coordination with relevant internal functions as well as external parties,
- Develop and implement a strategy and process for acquisition, rapid access, management and analysis of spontaneous reporting data sources suitable for signal detection and management,
- Develop Signal Detection and Management Governance and Processes to ensure proper identification, management, follow-up and tracking of all signal and safety issues; ensure synergy of Signal Detection Process with other processes,
- Lead various transversal teams to define and implement a new Signal Detection Business Process (20 members from the US and Europe),
- Manage team resources to ensure timely completion of all activities (4 direct reports, \$ 1 million budget).

Jan 2007 to Aug 2012
Senior Director and Deputy Head, GPE Epidemiology,
Sanofi

- Build and lead a team responsible for the management and analyses of various observational databases for in-house epidemiologic studies to support Pharmacovigilance,
- Develop and Implement Governing Documents and Processes for Analyses of Existing Databases
- Develop and implement comprehensive pharmacoepidemiologic programs to maximize the most efficient and successful epidemiologic safety programs,
- Advise Head GPE Epidemiology to ensure integrated management of all scientific, technical and administrative matters within GPE Epidemiology and in collaboration with other functions,
- Supervise epidemiology contribution to the development and updates of Risk Management Plan,
- Serve as an expert and provide advice on various fields: epidemiologic and statistical methods, quantitative benefit risk analysis and data mining/signal detection,
- Represent Sanofi in various epidemiology/signal management working group in collaboration with external parties:
 - European Pharmacoepidemiological Research on Outcomes of Therapeutics in a European Consortium (PROTECT)
 - Lead a case study team in the PROTECT project in developing methods for benefit-risk monitoring of medicines
 - Represent the company in various PhRMA initiatives: PhRMA – OMOP, PhRMA – suicidality, and other groups

May 2005 to Dec 2005
Acting Head, Pharmacoepidemiology,
sanofi-aventis

- Lead Pharmacoepidemiology team in the absence of Head due to illness in the transition period during the merger between Aventis and sanofi,
- Lead the development, coordination, and implementation of the strategy to incorporate state-of-the-art epidemiology practices in all Pharmacoepidemiology studies for investigational and post-marketing products
- Lead Pharmacoepidemiology projects as part of Risk Management Activities, including but not limited to development of RMP document and Pharmacovigilance Plan,
- Lead the development and implementation of a strategy and process for acquisition, rapid access and analysis of data sources capable of providing critical background incidence and prevalence data, patterns of drug utilization, independent risk factors for specific adverse events, etc., to facilitate analysis and interpretation of critical product safety issues,
- Lead transversal interactions and collaborations with other departments within Sanofi, especially Pharmacovigilance, Medical Affairs, Regulatory Affairs, Pre-clinical and Clinical Development, Marketing and others and serve as lead consultant to provide Pharmacoepidemiology expertise to other groups within the company,
- Be responsible for and lead the communication, presentations, and discussions of Pharmacoepidemiology-related issues with Regulatory Authorities around the world,

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- Lead external scientific collaborations with regulatory agencies, other pharmaceutical companies and academia in the US, Europe and Asia
- Mentor team personnel: Professional and career development, state-of-the-art epidemiology methodologies and practices, post-marketing and investigational Pharmacoepidemiology and safety monitoring/data analysis techniques, and regulatory guidelines
- Manage Pharmacoepidemiology department budget (around \$ 3 million in 2005).

Feb 2001 to Dec 2006

Various positions with increasing responsibility, Pharmacoepidemiology, sanofi-aventis

- Build and lead a team responsible for the management and analyses of various observational databases for in-house epidemiologic studies to address safety issues of all products and to support various functions including Clinical, Health Economics and Marketing,
- Evaluate and validate applications of existing and novel epidemiologic methods, including benefit-risk analysis methods, on existing observational databases,
- Develop, write and maintain the standards for using epidemiologic tools to demonstrate drug safety,
- Supervise epidemiology contribution to the development and updates of Risk Management Plan,
- Lead and monitor epidemiology studies to ensure appropriate methods are used, including formulating hypotheses, study design, analysis and report writing,
- Provide consultation, teaching and guidance on epidemiology and other quantitative methods to colleagues in the company,
- Prepare and justify annual budget and monitor expenses on a monthly basis (\$2 million annually),
- Supervise epidemiologists, analysts and SAS programmers (5 direct reports)

Jul 1999 to Feb 2001

Post-doctoral fellow, Collaborative Studies Coordinating Center, Department of Epidemiology and Biostatistics, University of North Carolina at Chapel Hill

- Design, analyze and publish epidemiologic studies on obesity, cardiovascular diseases, and antidepressant,
- Analyze large prospective cohort studies, including the Atherosclerosis Risk in Communities Study, Knowledge Attitude and Behavior among Native American Children Study, and American Cancer Society-Cancer Prevention Study,
- Manage various databases utilizing PC and UNIX System,
- Provide epidemiologic and statistical method consultation to clinicians and to the graduate students,
- Provide critical review of published literature,
- Serve as a reviewer of manuscripts to be published in the *American Journal of Epidemiology*, *Obesity Research*, *Epidemiology*, *Journal of the American Geriatrics Society*, and *International Journal of Epidemiology*.

Jul 1996 to Jul 1999

**Graduate Research Assistant - Epidemiologist,
Collaborative Studies Coordinating Center,
Department of Epidemiology and Biostatistics,
University of North Carolina at Chapel Hill**

- Design, evaluate and test existing and novel epidemiologic methods on the associations between obesity and mortality,
- Design, analyze, and publish studies on obesity and mortality using Cancer Prevention Study Database,
- Design, analyze, and publish studies on weight change and hypertension using the Atherosclerosis Risk in Communities Study database,
- Design, analyze, and publish studies on obesity as well as attitudes and behaviors toward body weight among Native American children,
- Develop, test, and publish spline function methods for analyses of obesity and mortality; and
- Organize a seminar series on Nutritional Epidemiology.

Aug 1994 to May 1996

**Graduate Research Assistant,
Department of Public Health Science,
Wake Forest University School of Medicine**

- Analyze and publish epidemiologic studies on vitamin C, cardiovascular risk factors, and end-stage renal disease,
- Analyze large prospective cohort studies (Insulin Resistance and Atherosclerosis Study, Kidney Outcomes Predictions and Evaluations Study).

Jan 1991 to Aug 1994

**Instructor, Department of Statistics,
Bogor Agricultural University
Indonesia**

- Design, analyze, and report studies on (1) Food Security System in West Java (2) The Impact of Forestation on Socioeconomic Status of the Participating Farmers, and
- Provide statistical consultation to the investigators in the Primate Research Center.

PUBLIC PRIVATE PARTNERSHIP

Aug 2015 - present

**Scientific Advisory Committee Member
Innovation in Medical Evidence Development and Surveillance (IMEDS)
Reagan – Udall Foundation, FDA**

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Mar 2007 to present
Adjunct Faculty, School of Public Health
University of North Carolina at Chapel Hill

- Supervise Ph.D. students and Post-doctoral fellows (currently supervise 1 Ph.D. student, Summer interns),
- Perform epidemiologic studies on epidemiology methods, causes and consequences of obesity, and cardiovascular disease.

Feb 2011 to March 2014
Steering Committee Member
IMI PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium)

Aug 2011 to March 2014
Management Team and Acomplia Team Leader
PROTECT Benefit – Risk Group

- Lead team members from regulatory agency, academia and industry to evaluate and develop various quantitative BR methods,
- Serve in the management team,
- Lead the presentation of the results in various scientific meetings and publication in peer reviewed journals.

Aug 2008 to June 2013
Extended Consortium, PhRMA OMOP (Observational Medical Outcome Partnership)

- Participate in the development of OMOP protocol
- As extended consortium member, test the CDM and other methods in different databases not used by OMOP, especially in the UK Medical Records

TEACHING EXPERIENCE

Jul 1997 to Jul 1998
Graduate Teaching Assistant, Department of Epidemiology,
University of North Carolina at Chapel Hill

- EPID 160: Fundamentals of Epidemiology
- EPID 268: Quantitative Methods in Epidemiology
- EPID 259: Nutritional Epidemiology
- EPID 260: Obesity Epidemiology

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Jan 1991 to Aug 1994
Instructor, Department of Statistics,
Bogor Agricultural University
Indonesia

- Introductory Statistics
- Introductory Probability
- Advanced Calculus, and
- Theory of Statistics

Feb 1991 to Aug 1994
Founder, Director, Teacher,
PRISMA Learning Center
Bogor, Indonesia

- Start a new company (PRISMA) providing teaching services for high school students,
- Find investors and recruit teachers,
- Develop marketing program and teaching curricula for Mathematics, Physics, and Chemistry,
- Teach Mathematics (high school students),
- With 35 teachers and 1,500 students, PRISMA became the best and most respected as well as popular learning center in the city.

Aug 1986 to Jan 1991
Teacher, Bogor Science Club (BSC) Learning Center
Bogor, Indonesia

- Teach Mathematics (elementary, junior, and high school students) and Chemistry (high school students)

Aug 1986 to Dec 1990 Undergraduate Teaching Assistant, Bogor Agricultural University, Bogor, Indonesia

- Chemistry
- Mathematics
- Introductory Statistics

PUBLICATIONS: REFEREED ARTICLES

1. Tcherny-Lessenot S, Wang Y, Juhaeri J, Kurz X, Auclert L, Caubel P. Negative control study on the risk of acute myocardial infarction associated with the use of antibiotics using a US database (submitted).
2. Grimaldi-Bensouda L, Causeret-Kelley S, Wang Y, Kurz X, Auclert L, Juhaeri J, Abenheim L, Rossignol M, Tcherny-Lessenot S. Cross-databases validation analyses for the detection of no-risk: the case of antibiotics exposure and acute myocardial infarction (submitted).
3. Wu C, Koren A, Thammakhoune J, Wu J, Kehemir H, Tcherny-Lessenot H, Lin S, Juhaeri J. Identifying hospitalizations related to heart failure in dronedarone users who are supplementary Medicare beneficiaries (submitted).
4. Wu C, Tcherny-Lessenot S, Dai W, Wang Y, Kehemir H, Auclert L, Wu J, Caubel P, Juhaeri J. Risk of peripheral neuropathy for dronedarone compared to other antiarrhythmics (submitted).
5. Colilla S, Yom Tov E, Zhang L, Kurzinger ML, Tcherny-Lessenot S, Penfornis C, Jen S, Gonzalez D, Caubel P, Welsh S, Juhaeri J. Validation of New Signal Detection Methods for Web Query Log Data Compared to Signal Detection Algorithms Used With FAERS. *Drug Saf* (2017). doi:10.1007/s40264-017-0507-4
6. Wu J, Juhaeri J. The US Food and Drug Administration's Risk Evaluation and Mitigation Strategy (REMS) Program - Current Status and Future Direction. *Clin Ther*. 2016 Nov 30. pii: S0149-2918(16)30845-1. doi: 10.1016/j.clinthera.2016.11.007. [Epub ahead of print] PubMed PMID: 27914632.
7. Bérard A, Sheehy O, Kurzinger ML, Juhaeri J. Intranasal triamcinolone use during pregnancy and the risk of adverse pregnancy outcomes. *J Allergy Clin Immunol*. 2016 Apr 1. pii: S0091-6749(16)00262-1. doi: 10.1016/j.jaci.2016.01.021. [Epub ahead of print] PubMed PMID: 27045580.
8. Hughes D, Waddingham E, Mt-Isa S, Goginsky A, Chan E, Downey GF, Hallgreen CE, Hockley KS, Juhaeri J, Lieftucht A, Metcalf MA, Noel RA, Phillips LD, Ashby D, Micallef A; PROTECT Benefit-Risk Group. Recommendations for benefit-risk assessment methodologies and visual representations. *Pharmacoepidemiol Drug Saf*. 2016 Jan 22. doi: 10.1002/pds.3958. [Epub ahead of print] PubMed PMID: 26800458
9. Radawski C, Morrato E, Hornbuckle K, Bahri P, Smith M, Juhaeri J, Mol P, Levitan B, Huang HY, Coplan P, Li H; BRACE Special Interest Group. Benefit-Risk Assessment, Communication, and Evaluation (BRACE) throughout the life cycle of therapeutic products: overall perspective and role of the pharmacoepidemiologist. *Pharmacoepidemiol Drug Saf*. 2015 24: 1233–1240.
10. Udo R, Tcherny-Lessenot S, Brauer R, Dolin P, Irvine D, Wang Y, Auclert L, Juhaeri J, Kurz X, Abenheim L, Grimaldi L, De Bruin ML. The risk of acute liver injury associated with the use of antibiotics-evaluating robustness of results in the pharmacoepidemiological research on outcomes of therapeutics by a European consortium (PROTECT) project. *Pharmacoepidemiol Drug Saf*. 2016 Mar;25 Suppl 1:47-55
11. Wu J, Zhang L, Vaze A, Lin L, Juhaeri J. Risk of Wernicke's Encephalopathy and Cardiac Disorders in Patients with Myeloproliferative Neoplasm. *Cancer Epidemiol* 2015; 39(2): 242-9.
12. Hallgreen CE, van den Ham HA, Mt-Isa S, Ashworth S, Hermann R, Hobbiger S, Luciani D, Micallef A, Thomson A, Wang N, van Staa TP, Downey G, Hirsch I, Hockley K, Juhaeri J, Metcalf M, Mwangi J, Nixon R, Peters R, Stoeckert I, Waddingham E, Tzoulaki I, Ashby D, Wise L. Benefit-risk assessment in a post-market setting: a case study integrating real-life experience into benefit-risk methodology. *Pharmacoepidemiol Drug Saf*. 2014 Sep;23(9):974-83.
13. Mt-Isa S, Hallgreen CE, Wang N, Callréus T, Genov G, Hirsch I, Hobbiger SF, Hockley KS, Luciani D, Phillips LD, Quartey G, Sarac SB, Stoeckert I, Tzoulaki I, Micallef A, Ashby D; IMI-PROTECT benefit-risk participants. Collaborators: Amzal B, Ashby D, Ashworth S, Asiimwe A, Bring J, Callreus T,

- Chan EK, Dierig C, Downey G, Gelb D, Genov G, Goginsky A, Hallgreen C, Hermann R, Hirsch I, Hobbiger S, Hockley K, Hughes D, Juhaeri J, Kuhls S, Lieftucht A, Luciani D, Metcalf M, Micallef A, Mt-Isa S, Mwangi J, Nixon R, Noel R, Pears J, Peters R, Phillips L, Quartey G, Sarac SB, Shepherd S, Stoeckert I, Swain EJ, Thomson A, Titeux L, Tzoulaki I, van den Ham R, van Staa T, Waddingham E, Wang N, Wise L. Balancing benefit and risk of medicines: a systematic review and classification of available methodologies. *Pharmacoepidemiol Drug Saf.* 2014 Jul;23(7):667-78.
14. Wu J, Juhaeri J, Wang L, Wu Chuntao, Dai W. Post-marketing Drug Safety Management. *Chinese J Pharmacoepidemiol* 2014; 23(4): 223-7.
 15. Wu J, Thammakhoune J, Dai W, Koren A, Tcherny-Lessenot S, Wu C, Caubel P, Juhaeri J. Assessment of Dronedarone Utilization Using US Claims Databases. *Clin Ther.* 2014 Jan 30 [Epub ahead of print] PubMed PMID: 24486334.
 16. Gao S, Dai W, Zhang L, Juhaeri J, Wang Y, Caubel P. Risk of Cardiovascular Events, Stroke, Congestive Heart Failure, Interstitial Lung Disease, and Acute Liver Injury: Dronedarone versus Amiodarone and Other Antiarrhythmics. *J At Fib* 2014; 6(4): 25-32.
 17. Gao S, Juhaeri J, Reshef S, Dai W. Association between body mass index and suicide, and suicide attempt among British adults: the health improvement network database. *Obesity* 2013 Mar; 21(3): E334-42
 18. Gao S, Juhaeri J, Schiappacasse HA, Koren AT, Dai WS. Evaluation of Dronedarone Use in the US Patient Population Between 2009 and 2010: A Descriptive Study Using a Claims Database. *Clin Ther.* 2011 Oct;33(10):1483-1490.
 19. Johnson ES, Smith DH, Thorp ML, Yang X, Juhaeri J. Predicting the risk of end-stage renal disease in the population-based setting: a retrospective case-control study. *BMJ Nephrol* 2011 May 5;12:17
 20. Juhaeri J, Gao S, Dai WS. Incidence Rates of Heart Failure, Stroke, and Acute Myocardial Infarction among Type 2 Diabetic Patients Using Lantus and Other Insulin. *Pharmacoepidemiol Drug Saf.* 2009 Jun;18(6):497-503
 21. Han E, Truesdale K, Taber D, Cai J, Juhaeri J, Stevens S. Impact of overweight and obesity on hospitalization: Race and Gender differences. *Int Journal Obesity* 2009; 33(2): 249-56.
 22. Gao S, Juhaeri J, Wanju Dai WS. The Association of the Incidence Rate of Seizures and Body Mass Index in UK Adults: the Health Improvement Network Database. *Obesity* 2008; 16: 2126-32
 23. Cannon GW, Holden WL, Juhaeri J, Dai W, Scarazzini L, Stang P. Adverse events with disease-modifying antirheumatic drugs: a cohort study of leflunomide compared with other DMARDs. *J Rheum* 2004; 31:1906-11.
 24. Holden WL, Juhaeri J, Dai W. Benefit-risk analysis: examples using quantitative methods. *Pharmacoepidemiology and Drug Safety* 2003;12:693-7.
 25. Stevens J, Story M, Ring K, Murray DM, Cornell CE, Juhaeri, Gittelsohn J. The impact of the Pathways intervention on psychosocial variables related to diet and physical activity in American Indian schoolchildren. *Prev Med.* 2003; 37 (Suppl 1):S70-9
 26. Holden WL, Juhaeri J, Dai W. Benefit-risk analysis: a proposal using quantitative methods. *Pharmacoepidemiology and Drug Safety* 2003;12:611-6.
 27. Juhaeri, Stevens J, Chambless LE, Nieto FJ, Schreiner P, Jones D, Arnett D, Cai J. Association between weight loss and the remission of hypertension: The Atherosclerosis Risk in Communities Study. *Preventive Medicine* 2003; 36: 330-9.
 28. Juhaeri, Stevens J, Jones D, Arnett D. Associations of aging and birth cohort with body-mass index in a bi-ethnic cohort: The Atherosclerosis Risk in Communities Study. *Obesity Research* 2003; 11: 426-33.
 29. Juhaeri, Stevens J, Chambless LE, Tyroler HA, Rosamond W, Nieto FJ, Schreiner P, Jones D, Arnett D. Association between weight gain and incident hypertension in a bi-ethnic cohort: The Atherosclerosis Risk in Communities Study. *International Journal of Obesity* 2002; 26: 58-64.

30. Juhaeri, Stevens J, Chambless LE, Tyroler HA, Harp J, Jones D, Arnett D. Weight change among self-reported dieters and non-dieters in the Atherosclerosis Risk in Communities Study. *European Journal of Epidemiology* 2002; 17:917-23.
31. Stevens J, Juhaeri, Cai J, G Evans. The impact of body-mass index change on changes in common carotid artery wall thickness in The Atherosclerosis Risk in Communities Study. *Obesity Research* 2002; 10:1000-7
32. Stevens J, Ahn K, Juhaeri, Houston D, Steffan L, Couper D. Dietary Fiber Intake and Glycemic Index and Incidence of Diabetes in African-American and White Adults: The ARIC Study. *Diabetes Care* 2002 25: 1715-21.
33. Stevens J, Juhaeri, Cai J, Jones DW. The effect of decision rules on the choice of a body mass index cutoff for obesity: Examples from African American women. *American Journal of Clinical Nutrition* 2002; 75:986-92.
34. Stevens J, Juhaeri, Cai J. Re: Changes in body mass index prior to baseline among participants who are ill or who die during the early years of follow-up (Authors' reply to the letter to the editor). *American Journal of Epidemiology* 2001; 154:685-6.
35. Story M, Stevens J, Evans M, Cornell C, Juhaeri, Gittelsohn J, Going S, Clay T, Murray D. Weight loss attempts and attitudes toward body size, eating and physical activity in American Indian children: Relationships to weight status and gender. *Obesity Research* 2001; 9:356-63.
36. Stevens J, Juhaeri, Cai J. Changes in body mass index prior to baseline among participants who are ill or who die during the early years of follow-up. *American Journal of Epidemiology* 2001; 153:946-53.
37. Knowles J, Stevens J, Juhaeri J, Farr S, Schriener P. Weight change associated with the use of antidepressants. *Gastroenterology* 2001; 120(5). DOI:10.1016/S0016-5085(08)81039-6
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HONORS

- January 1992: Young Researcher Award, *Indonesian Statistical Association and Department of Science and Technology of the Republic of Indonesia*
- August 1989: Indonesian National Student Award, *Department of Education and Culture of the Republic of Indonesia*
- August 1989: Indonesian Statistical Student Award, *Indonesian Statistical Association, Jakarta, Indonesia*

PROFESSIONAL SERVICE

Professional societies

- International Society of Pharmacoepidemiology
- Society for Epidemiologic Research
- DIMACS (Discrete Mathematics & Theoretical Computer Sciences) Working Group on Adverse Event/Disease Reporting, Surveillance, and Analysis
- North American Association for the Study of Obesity

Invited reviewer

- American Journal of Epidemiology
- Epidemiology
- International Journal of Epidemiology
- Pharmacoepidemiology and Drug Safety
- Journal of the American Geriatrics Society
- Obesity Research
- International Journal of Obesity

COMPUTING SKILLS

- Procedure-based Software: SAS, SUDAAN, MINITAB, SYSTAT, STATA, EPIINFO
- Function-based Software: S-plus, C++, Pascal, Fortran, Basic

Jan 2017

LANGUAGES

- Excellent: Indonesian, Sundanese
- Elementary: Portuguese, French

INTEREST AND ACTIVITIES

- Fishing and other outdoor activities, travel, sports, history

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References are available upon request.