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Global Medical Affairs
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PROFILE

A leader in Pharmacovigilance, Real World Evidence and Epidemiology with almost two decades of leadership experience in Sanofi and public – private partnerships.

Experienced in all aspects of global pharmacovigilance and risk-management with a more than 20-year track record in cardiovascular, diabetes, oncology, and other therapeutic areas. Experienced in dealing with complex issues of benefit-risk and working productively with all pharma functional areas as well as with regulatory authorities from Phase I to Phase IV; a proven track record of managing teams and external collaborators in all aspects of safety, signal detection, and epidemiology.

Leadership in public-private collaborations between regulatory agencies, academia, and pharmaceutical industry in Patient Preference, Epidemiology and Benefit-Risk Evaluation in the US, Europe and Asia in developing methods and shaping policy and agenda on in drug decision making

- IMI – PREFER (a European Consortium Project to strengthen patient-centric decision making throughout the life cycle of medicinal products); leading team to evaluate why, when and how to evaluate patient perspectives in the whole drug lifecycle
- IMI – PROTECT (a European Consortium Project in Pharmacovigilance and Pharmacoepidemiology) – a project to evaluate various benefit-risk methods which are currently being implemented by the industry and among Regulators.
- PhRMA OMOP (Observational Medical Outcome Partnership), one of the first public projects in Big Data use, to inform the appropriate use of observational healthcare databases for studying the effects (risks and benefits) of medicinal products; participated in the development of the Methods Protocol. One of the results of OMOP, Common Data Model, is currently used in the FDA-Sentinel system and in various pharmaceutical companies, including Sanofi
- IMEDS (Innovation in Medical Evidence Development and Surveillance) – a program under Reagan-Udall Foundation linking FDA Sentinel and Public. Served as a Scientific Advisory Committee member to define the model of FDA Sentinel by industry and academia.

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"

BUSINESS

2017 IMD Business School
Business for Tomorrow Program,
Business & Leadership,
Lausanne, Switzerland

PROFESSIONAL EXPERIENCE

Jul 2017 to present – Head, Epidemiology and Benefit-Risk Evaluation, Global Medical Affairs, Sanofi

- Lead a global team responsible for the development, coordination, and implementation of the strategy to incorporate state-of-the-art approaches in Epidemiology, BR Evaluation, and Innovation for Sanofi products
- Lead transversal collaborations and collaboration with other Sanofi leaders in Pharmacovigilance, Medical Affairs, Regulatory Affairs, Pre-clinical and Clinical Development to ensure appropriate analyses of real world databases for BR evaluation and translation into business actions
- Lead innovative projects on Benefit-Risk Evaluation and Signal Detections
- Lead Pharmacoepidemiology projects to address safety issues, including but not limited to development of RMP documents, design and implementation of Post-Approval Safety Studies (PASS) or Post-Approval Efficacy Studies (PAES), evaluations of Risk Minimization measures (e.g. Drug Utilization Studies and Prescription Surveys), and responses to authorities
- Lead the communication on and implementation of structured, continuous, quantified benefit-risk assessment methods across the portfolio throughout the whole drug lifecycle, including BR of outcomes in real life settings
- Lead interactions with Regulators and other external stakeholders in relation to scientific methods, policy and best practices in Epidemiology, BR Evaluation, and Big Data Advanced Analytics and ensure Regulatory compliance
- Lead external scientific collaborations with regulatory agencies, industry and academia: for example, IMI-PREFER (Patient Preference in BR evaluation) and collaborations with Chinese FDA and Peking University

Sep 2015 to Jun 2017 – Head, Global Safety Sciences, Global Pharmacovigilance and Epidemiology, Sanofi

- Lead a global team (US, Europe and Asia) responsible for Safety Sciences to address safety issues (Pharmacoepidemiology, Data Mining, Signal Detection, Risk Management, Benefit Risk Evaluation and Pharmacovigilance Science, and Device) for Sanofi investigational and marketed products
- Lead innovative Big Data Projects utilizing advanced analytics, including Artificial Intelligence (AI) for Signal Detection and Assessment
- Lead transversal collaborations and work closely with leaders from other departments within Sanofi, especially Pharmacovigilance, Medical Affairs, Regulatory Affairs, Pre-clinical and Clinical Development to ensure appropriate analyses of real world databases and optimal use of the results to address safety issues
- Lead Pharmacoepidemiology projects to address safety issues throughout products lifecycle, 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), and responses to authorities
- Lead the development and implementation of a strategy and process for acquisition, rapid access and analysis of Big 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
- Lead interactions with Regulators and other external stakeholders in relation to scientific methods, policy and best practices in Epidemiology, BR Evaluation, and Signal Detection and ensure Regulatory compliance
- Lead external scientific collaborations with regulatory agencies, other pharmaceutical companies and academia: IMI-PREFER and IMEDS (Innovation in Medical Evidence Development and Surveillance), and Chinese FDA

Sep 2012 to Sep 2015 – Head, Pharmacoepidemiology and Signal Detection, Global Pharmacovigilance and Epidemiology, Sanofi

- Lead a team of experts responsible for the development and implementation of state-of-the-art epidemiology and signal detection methodologies and practices to address safety issues of Sanofi products
- Lead innovative Big Data Projects utilizing advanced analytics, including Artificial Intelligence (AI) for Signal Detection and Assessment

- 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
- 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
- Lead external scientific collaborations with regulatory agencies, other pharmaceutical companies and academia: for example, IMI-PROTECT (European consortium for pharmacoepidemiology research), FDA - IMEDS and collaboration with Shanghai ADR and Chinese ADR

May 2010 to Sep 2012 – Head, Signal Detection and Management, Global Pharmacovigilance and Epidemiology, 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 external scientific collaborations: IMI-PROTECT, PhRMA – OMOP (Observational Medical Outcomes Project)

Jan 2007 to May 2010 – Deputy Head, Pharmacoepidemiology, Global Pharmacovigilance and Epidemiology, Sanofi

- 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
- 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: PhRMA – OMOP, PhRMA – suicidality, and other groups

May 2005 to Dec 2005 – Acting Head, Pharmacoepidemiology, Global Pharmacovigilance and Epidemiology, 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 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
- 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, industry and academia in US, Europe and Asia

- Mentor team personnel: Professional and career development, state-of-the-art epidemiology methodologies and practices, post-marketing and investigational Phamracoepidemiology and safety monitoring/data analysis techniques, and regulatory guidelines

Feb 2001 to Dec 2006 – Various positions with increasing responsibility, Pharmacoepidemiology, Global Pharmacovigilance and Epidemiology, 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
- 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, incl. 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
- 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 associations between obesity and mortality
- Design, analyze, and publish studies on obesity and mortality: Cancer Prevention Study, Atherosclerosis Risk in Communities Study, Pathways (attitudes and behaviors toward body weight among Native American children

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 and (2) The Impact of Forestation on Socioeconomic Status of the Participating Farmers
- Provide statistical consultation to the investigators in the Primate Research Center

PUBLIC-PRIVATE PARTNERSHIPS

Jun 2016 to present – Industry Lead, Methods Working Group, IMI PREFER - a five-year European public-private research project on patient preferences in BR evaluation throughout drug lifecycle

- Lead team of academia and industry representatives to evaluate why, when and how (methods) to evaluate patient preferences in the drug lifecycle

- Serve in the Steering Committee and Management team
- Lead the presentation of results in various scientific meetings and publication in peer reviewed journals

Aug 2015 to Aug 2016 – **Scientific Advisory Committee Member, Innovation in Medical Evidence Development and Surveillance (IMEDS), Reagan – Udall Foundation, FDA**

- Serve as a Scientific Advisory Committee member to define the model of FDA Sentinel

Feb 2011 to Mar 2014 – **Leader, Rimonabant Case Study Team, IMI PROTECT (Pharmacoepidemiological Research on Outcomes of Therapeutics by a European ConsorTium**)

- Lead Rimonabant Case Study team with representatives from regulatory agencies, academia and industry to evaluate and develop various quantitative BR methods
- Serve in the Scientific Committee and Management team
- Lead the presentation of results in various scientific meetings and publication in peer reviewed journals

Aug 2008 to Jun 2013 – **Extended Consortium Member, PhRMA OMOP (Observational Medical Outcome Partnership)**

- Participate in the development of OMOP protocol
- Test the CDM and other methods in different databases, including the the UK Medical Records database

TEACHING EXPERIENCE

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

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

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

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

- Found investors, recruited teachers, developed marketing program and teaching curricula for Mathematics, Physics, and Chemistry
- Taught Mathematics
- With 35 teachers and 1,500 students, PRISMA became the best and most respected learning center in the city

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

- 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 and

- Introductory Statistics

HONORS

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

PROFESSIONAL ACTIVITIES

Professional societies

- International Society of Pharmacoepidemiology
- International Society of Pharmacovigilance
- Society for Epidemiologic Research

Invited reviewer

- Pharmacoepidemiology and Drug Safety
- Clinical Therapeutics
- American Journal of Epidemiology
- International Journal of Epidemiology

COMPUTING SKILLS

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

LANGUAGES

- Native: Indonesian, Sundanese
- Full professional proficiency: English
- Elementary proficiency: Portuguese, French

INTEREST AND ACTIVITIES

- Fishing and other outdoor activities, travel, history

REFERENCES

References are available upon request.

PUBLICATIONS: PEER-REVIEWED ARTICLES

1. Whichello C., Levitan B, Juhaeri J, Patadia V, DiSantostefano R, Pinto C-A, de Bekker-Grob EW. Appraising patient preference methods for decision-making in the medical product lifecycle: An empirical comparison. BMC Medical Informatics and Decision Making MIDM-D-19-00502 (in press)
2. van Overbeeke E, Janssens R, Whichello C, Schölin-Bywall K, Sharpe J, Nikolenko N, Phillips BS, Guiddi P, Pravettoni P, Vergani L, Marton G, Cleemput I, Simoens S, Kübler J, Juhaeri J, Levitan B, de Bekker-Grob EW, Veldwijk J, Huys I. Design, Conduct and Use of Patient Preference Studies in the Medical Product Life Cycle: a Multi-method Study. Frontier. doi: 10.3389/fphar.2019.01395
3. Juhaeri J. Benefit-risk evaluation: the past, present and future. Ther Adv Drug Saf. 2019 Aug 26;10:2042098619871180. doi: 10.1177/2042098619871180. eCollection 2019. Review. PubMed PMID: 31489173; PubMed Central PMCID: PMC6712756.
4. Janssens R, Huys I, van Overbeeke E, Whichello C, Harding S, Kübler J, Juhaeri J, Ciaglia A, Simoens S, Stevens H, Smith M, Levitan B, Cleemput I, de Bekker-Grob E, Veldwijk J. Opportunities and challenges for the inclusion of patient preferences in the medical product life cycle: a systematic review. BMC Med Inform Decis Mak. 2019 Oct 4;19(1):189. doi: 10.1186/s12911-019-0875-z. PubMed PMID: 31585538; PubMed Central PMCID: PMC6778383.
5. Bate A, Hornbuckle K, Juhaeri J, Motsko SP, Reynolds RF. Hypothesis-free signal detection in healthcare databases: finding its value for pharmacovigilance. Ther Adv Drug Saf. 2019 Aug 5;10:2042098619864744. doi:10.1177/2042098619864744. eCollection 2019. PubMed PMID: 31428307; PubMed Central PMCID: PMC6683315.
6. Gavrielov-Yusim N, Kürzinger ML, Nishikawa C, Pan C, Pouget J , Epstein L BH , Dekel-Rotman D,Tcherny-Lessenot S, Lin S, Hamelin B, Juhaeri J. Comparison of machine learning and natural language processing methods in social media -based signal detection. Pharmacoepidemiol Drug Saf. 2019;1–9.
7. Whichello C, van Overbeeke E, Janssens R, Schölin-Bywall K, Russo S, Veldwijk J, Cleemput I, Juhaeri J, Levitan B, Kübler J, Smith M, Hermann R, Englbrecht M, Hueber A, Comaneuscu A, Harding S, Simoens S, Huys I, de Bekker-Grob EW. Factors and situations affecting the value of patient preference studies: semi-structured interviews in Europe and the US. Front. Pharmacol. | doi: 10.3389/fphar.2019.01009
8. Janssens R, Russo S, van Overbeeke E, Whichello C, Harding S, Kübler J, Juhaeri J, Bywall KS, Comanescu A, Hueber A, Englbrecht M, Nikolenko N, Pravettoni G, Simoens S, Stevens H, Hermann R, Levitan B, Cleemput I, de Bekker-Grob E, Veldwijk J, Huys I. Patient Preferences in the Medical Product Life Cycle: What do Stakeholders Think? Semi-Structured Qualitative Interviews in Europe and the USA. The Patient - Patient-Centered Outcomes Research (2019) 12:513–526. doi: 10.1007/s40271-019-00367-w. [Epub ahead of print] PubMed PMID: 31222436.
9. Soekhai V, Whichello C, Levitan B, Veldwijk J, Pinto CA, Donkers B, Huys I, van Overbeeke E, Juhaeri J, de Bekker-Grob EW. Methods for exploring and eliciting patient preferences in the medical product lifecycle: a literature review. Drug Discov Today. 2019 May 8. pii: S1359-6446(18)30537-3. doi: 10.1016/j.drudis.2019.05.001. [Epub ahead of print] PubMed PMID: 31077814.
10. van Overbeeke E, Whichello C, Janssens R, Veldwijk J, Cleemput I, Simoens S, Juhaeri J, Levitan B, Kübler J, de Bekker-Grob E, Huys I. Factors and situations influencing the value of patient preference studies along the medical product lifecycle: a literature review. Drug Discov Today. 2019 Jan;24(1):57-68
11. Wu C, Juhaeri J, Sharma K, Lin S, Kumar M, Pan S, Boyle P. No increased risk of breast cancer in patients exposed to insulin glargine compared to human NPH insulin. Diabetology (Under review).
12. Zhong VW, Juhaeri J, Cole SR, Shay CM, Gordon-Larsen P, Kontopantelis E, Mayer-Davis EJ. Proximal HbA1C Level and First Hypoglycemia Hospitalization in Adults with Incident Type 2 Diabetes. J Clin Endocrinol Metab. 2019 Jan 3. doi: 10.1210/jc.2018-01402. [Epub ahead of print] PubMed PMID: 30608562.
13. Kürzinger ML, Schück S, Texier N, Abdellaoui R, Faviez C, Pouget J, Zhang L, Tcherny-Lessenot S, Lin S, Juhaeri J. Web-Based Signal Detection Using Medical Forums Data in France: Comparative Analysis. J Med Internet Res. 2018 Nov 20;20(11):e10466. doi: 10.2196/10466. PubMed PMID: 30459145.
14. de Bekker-Grob EW, Juhaeri J, Kihlbom U, Levitan B et al. Giving patients' preferences a voice in the medical product lifecycle: why, when and how?: The public-private PREFER project: Work package 2. ISPOR Value & Outcomes Spotlight, p. 19 19-21 21, 2018
15. Wu C, Tcherny-Lessenot S, Dai W, Wang Y, Kechemir H, Gandhi S, Lin S, Juhaeri J. Assessing the Risk for Peripheral Neuropathy in Patients Treated With Dronedarone Compared With That in Other Antiarrhythmics. Clin Ther. 2018 Mar;40(3):450-455.
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17. Zhong VW, Juhaeri J, Cole SR, Shay CM, Gordon-Larsen P, Kontopantelis E, Mayer-Davis EJ. HbA(1C) variability and hypoglycemia hospitalization in adults with type 1 and type 2 diabetes: A nested case-control study. J Diabetes Complications. 2018 Feb;32(2):203-209. doi: 10.1016/j.jdiacomp.2017.10.008. Epub 2017 Oct 23. PubMed PMID: 29242016.
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19. Zhong VW, Crandell JL, Shay CM, Gordon-Larsen P, Cole SR, Juhaeri J, Kahkoska AR, Maahs DM, Seid M, Forlenza GP, Mayer-Davis EJ. Dietary intake and risk of non-severe hypoglycemia in adolescents with type 1 diabetes. J Diabetes Complications. 2017 Aug;31(8):1340-1347. doi: 10.1016/j.jdiacomp.2017.04.017. Epub 2017 Apr 20. PubMed PMID: 28476567; PubMed Central PMCID: PMC5526710.
20. 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
21. 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.
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24. 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.
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28. 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,Micaleff 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, Micaleff 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.
29. Wu J, Juhaeri J, Wang L, Wu Chuntao, Dai W. Post-marketing Drug Safety Management. Chinese J Pharmacoepidemiol 2014; 23(4): 223-7.
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33. 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.
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36. 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.
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