

リスク最小化策の評価方法の研究に関する報告リスト

2013年3月11日

「リスク最小化活動の効果の評価方法の検討に向けた準備」に関する研究」班

リスク最小化策の有効性の測定に関する論文

2013年3月11日現在

著者名 Authors	論文名 Title	雑誌名 Journal	備考 Memo
Luis Prieto, et. al. (EMA)	Evaluation of the effectiveness of risk minimization measures	Pharmacoepidemiology and Drug Safety 2012; DOI: 10.1002/pds.3305	評価には、施策の実施状況の確認と、副作用発現・重症化の軽減の測定が必要。"Dual evidence of RMM effectiveness"
Irina Caplanusi, et al (EMA)	Effectiveness of Risk Minimisation Measures: A Review of Centrally Authorised Products in the EU	Pharmacoepidemiology and Drug Safety Volume 21, Issue Supplement s3, pages 219, August 2012	2006 から 2009 EU で中央承認された医薬品について、追加のリスク最小化策の有効性を EMA がレビュー
FDA	<u>Risk evaluation and mitigation strategy assessments: Social science methodologies to assess goals related to knowledge</u>	June 7, 2012 Docket No. FDA-2012-N-0408 Issue Paper	重要なリスクについての医療従事者および患者の認知度を調査 Survey により確認
Daniel R. Levinson (Office of Inspector General)	<u>FDA lacks comprehensive data to determine whether REMS improve drug safety</u>	OEI-04-11-00510 Feb. 2013	2008 から 2011 FDA が承認した 199 REMS の有効性について米国保健福祉省の監察長官室がレビュー
Susan Nicholson et al	Pharmaceutical industry perspective on risk evaluation and mitigation strategies: manufacturer take heed	Expert Opin. Drug Saf. 2012; 11(2): 299-314	2011 年 10 月までに承認された REMS をレビュー。REMS 評価の事例として、理解度調査やセンチネル利用による事象発現率がある。
Inge M. Zomerdijk, Fakhredin A. Sayed-Tabatabaei, et al.	Risk minimization activities of centrally authorized Products in the EU. A descriptive study.	Drug Safety 2012; 35 (4): 299-314	1995 Jan ~ 2010 Jan 中央承認された 391 の有効成分で 2005 年 11 月の新規制前後で追加のリスク最小化策がどのように変化したかレビュー
Lenhangmbong Nkeng, Anne-Marine Cloutier, et al.	Impact of regulatory guidances and drug regulation on risk minimization interventions in drug safety. A systematic review.	Drug Safety 2012; 35(7):535-546	2000-2004 と 2005-2009 年までの RMI (Risk Minimization Intervention)の各国の比較 (文献、当局 HP)したレビュー。RMI は US, EU, JP で増加
Donghui Tony Yu, Diane L. Seger, et al.	Impact of implementing alerts about medication black-box warnings in electronic health records.	Pharmacoepidemiology and Drug Safety 2011; 20(2):192-202	BBW の遵守状況を医療 DB で確認

リスク最小化策の有効性の測定に関する論文(製品)

著者名 Authors	論文名 Title	雑誌名 Journal	備考 Memo
Cheryl Enger et al	The effectiveness of varenicline medication guide for conveying safety information on patients: a REMS assessment survey	Pharmacoepidemiology and Drug Safety 2013; DOI: 10.1002/pds.3400	Varenicline (Chantix) メディケーションガイドの理解度について患者を対象に調査
Donnie Funch, Heather Norman, et al.	Adherence to recommended dosing and monitoring for mitoxantrone in patients with multiple sclerosis: a healthcare claims database study supplemented with medical records - the RETRO study	Pharmacoepidemiology and Drug Safety 2010; 19(5):448-456	Mitoxantrone 投与毎の血液・肝・LVEF 検査の遵守状況を診療報酬請求 DB、カルテから確認
Eduardo Carracedo-Martinez, Agustin Pia-Mprandeira, et al.	Impact of a health safety warning and prior authorisation on the use of piroxicam: a time-series study.	Pharmacoepidemiology and Drug Safety 2012; 21(3):281-284	Piroxicam 注意喚起、処方毎の使用許可による薬剤の使用の変化を医療 DB で確認

Anne Kehely, Cheryl Smith, et al.	Risk minimization method evaluation in Oncology.	Drug Info J 2011; 45(1):77-82	Pemetrexed 前投与薬（葉酸、VB12）による副作用発現の緩和（治験）および前投与実施状況・FU効果（市販後）を社内DBにより確認
Janet Shin, T. Craig Cheetham, et al.	The impact of the iPLEDGE program on isotretinoin fetal exposure in an integrated health care system.	J Am Acad Dermatol 2011; 65(6): 1117-25	Isotretinoin Risk minimization activities of centrally authorized Products in the EU のレファレンス 33
Allen Brinker, Cynthia Kornegay, et al.	Trends in adherence to a revised risk management program designed to decrease or eliminate isotretinoin-exposed pregnancies: evaluation of the accutane SMART program.	Arch Dermatol 2005 May;141 (5): 563-9	Isotretinoin Risk minimization activities of centrally authorized Products in the EU のレファレンス 35
H.J.M.J. Crijns, S.M. Straus, et al.	Compliance with pregnancy prevention programmes of isotretinoin in Europe: a systematic review	Br. J Dermatol 2011 Feb; 164 (2): 238-44	Isotretinoin Risk minimization activities of centrally authorized Products in the EU のレファレンス 36
D. Miller, L. Bennett, et al.	A patient follow-up survey programme for alosetron: assessing compliance to and effectiveness of the risk management programme.	Aliment Pharmacol Ther 2006 Sep 1; 24 (5): 869-78	Alosetron Risk minimization activities of centrally authorized Products in the EU のレファレンス 34
Lin Chang, Kenneth Tong, et al.	Ischemic colitis and complications of constipation associated with the use of alosetron under a risk management plan: clinical characteristics, outcomes, and incidences.	Am J Gastroenterol 2010 Apr; 105 (4): 866-75	Alosetron Risk minimization activities of centrally authorized Products in the EU のレファレンス 37
Hollis K. Calingaert, et al.	Tysabri TOUCH prescriber program risk management program RiskMAP	[poster]. Presented at the 26th International Conference on Pharmacoepidemiology & Therapeutic Risk Management. 2010 Aug 19-22; Brighton	Tysabri Risk minimization activities of centrally authorized Products in the EU のレファレンス 38
Carmen P. Castaneda, Jerome B. Zeldis, et al.	A comprehensive risk minimization programme for preventing fetal exposure to lenalidomide.	Drug Saf 2008; 31 (9): 743-52	Lenalidomide Risk minimization activities of centrally authorized Products in the EU のレファレンス 39
A. Lledo, M. A. Dellva, et al.	Awareness of potential valvulopathy risk with pergolide and changes in clinical practice after label change: a survey among European neurologists.	Eur J Neurol. 2007 Jun;14(6):644-9	Pergolide 専門医に心血管系リスクについて認識および検査実施の状況調査
	Physicians awareness of safety information on the risk of cardiovascular pathology related to pergolide use in Japan.	International Society of Pharmacovigilance; Reims France Oct 6-9, 2009	Pergolide
Nobuhiro Ooba, Takuhiro Yamaguchi and Kiyoshi Kubota	The impact in Japan of regulatory action on prescribing of dopamine receptor agonists: analysis of a claims database between 2005 and 2008.	Drug Saf. 2011 Apr 1;34(4):329-38	Pergolide 処方の変化、検査実施についてJMDCデータベースを用いて
Maki Noguchi, Chieko Ishiguro, Ayumi Endo, Kazuhiro Matsui, Mie Ikeda. (Japan)	Drug use study of Doxorubicin using Japanese claim data.	Abstracts of the 28th International Conference on Pharmacoepidemiology & Therapeutic Risk Management, 23-26 Aug 2012, Barcelona, Spain	Doxorubicin 心機能検査の実施について医療データベースから調査 http://www.pharmacoepi.org/meetings/28/ICPE/ICPE2012_program_pages50-89.pdf

Kimura T, Shiosakai K, Takahashi S, Kobayashi M, Takeda Y, Sakaguchi M.	Quantitative evaluation of compliance with recommendation for sulfonylurea dose co-administered with DPP-4 inhibitors in Japan.	International Conference on Pharmacoepidemiology. Chicago IL. Aug 14-17, 2011.	DPP-4 inhibitor 低血糖（SU併用時）の問題。SU処方について調剤レセプトデータから調査
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