Recent Articles Relevant for PV (Safety) Writers from the "Medical Writing" Journal (MEW)

2020

Risk management plans in the EU: Managing safety concerns. Tiziana von Bruchhausen, Sven Schirp, ; Volume 29, Issue 3 (September, 2020) pp.30-35

2019

The 360° approach to authoring risk management plans. Sushma Materla; Volume 28, Issue 3 (September, 2019) pp. 56-61

Lay summaries and writing for patients: Where are we now and where are we going? Lisa Chamberlain James and Trishna Bharadia; Volume 28, Issue 3 (September, 2019) pp. 46-51

Same but different: Basic tools for biosimilar and generic pharmacovigilance writing. Tiziana von Bruchhausen, Kerstin Prechtel, and Stefanie Rechtsteiner; Volume 28, Issue 2 (June, 2019) pp. 45-52

Medical writing for generics throughout the life cycle. Sandra Götsch-Schmidt; Volume 28, Issue 2 (June, 2019) pp. 39-44

Writing biosimilar clinical study reports and submission documents – what to expect and what to consider. Katharina Brauburger and Sabrina Heisel-Stöhr; Volume 28, Issue 2 (June, 2019) pp. 33-38

Biosimilar development – an overview. Radovan Diana; Volume 28, Issue 2 (June, 2019) pp. 20-27

Regulatory pathways for development and submission activities. Yousuf Mohiuddin Mohammed; Volume 28, Issue 2 (June, 2019) pp. 8-17

2018

Expert seminar: The new EU RMP guidance and template in daily pharmacovigilance practice. Diana Radovan (Reports from the spring conference in Barcelona. Section editor: Amy Whereat); Volume 27, Issue 3 (Sep, 2018) pp. 46

In the Bookstores: An Introduction to Pharmacovigilance (Second Edition). Section editors: Alison McIntosh and Stephen Gilliver; Volume 27, Issue 2 (June, 2018) pp. 89-90
(this article is a book review)

Clinical trial disclosure and transparency: Regulation EU No. 536/2014 Public disclosure at the clinical trial level. Kathy B. Thomas; Volume 27, Issue 2 (June, 2018) pp. 7-17
(this article presents disclosure requirements for clinical safety data)

Pharmacovigilance for vaccines and immunotherapies: What does the medical writer need to know? Justina Orleans-Lindsay; Volume 27, Issue 1 (March, 2018) pp. 35-38

Allergen immunotherapy in the European regulatory environment. Ulrike Lehnigk; Volume 27, Issue 1 (March, 2018) pp. 30-34 *(this article presents safety collection and reporting requirements for allergen immunotherapies)*

HIV vaccine clinical trials: An overview. Jackline Odhiambo; Volume 27, Issue 1 (March, 2018) pp. 23-29
(this article includes safety considerations in vaccine development)

2017

EMA releases the revised Good Pharmacovigilance Practices Module V - updated guidance on risk management plans. Tiziana von Bruchhausen and Sven Schirp; Volume 26, Issue 3 (September, 2017) pp. 48- 51

Reporting non-interventional post-authorisation safety studies (NI-PASS). Gregory Morley; Volume 26, Issue 3 (September, 2017) pp. 38-41

Regulatory submissions of non-interventional post-authorisation safety studies: Challenges for data interpretation and comparisons with clinical data. James Visanji; Volume 26, Issue 3 (September, 2017) pp. 35-37

Odd cases and risky cohorts: Measures of risk and association in observational studies. Tom Lang; Volume 26, Issue 3 (September, 2017) pp. 12-16

2016

Patient education in clinical trials and throughout the product lifecycle. Susan M. Harris and Christopher G. Kelly; Volume 25, Issue 4 (December, 2016) pp. 23-29

RMP public summary reloaded: Revision 2 of GVP Module V. Tiziana von Bruchhausen and Stefanie Rechtsteiner (Medical Communications; Section editor: Lisa Chamberlain James); Volume 25, Issue 3 (September, 2016) pp. 65-68

Study design made easy. Diogo Bruno; Volume 25, Issue 3 (September, 2016) pp. 26-30

Regulatory Matters: The growing need for drug safety documents. Section editor: Greg Morley; Volume 25, Issue 2 (June, 2016) pp. 46-47

Writing for pharmaceutical or medical device companies: A survey of entry requirements, career paths, quality of life, and personal observations. Steven Walker, Jane Opie, Sophia Whitman, Wendy Critchley, Kristin L Hood, Vicki M Houle, Michael Todd, Tahin Manjur, Yvonne Anderson, and John Gonzalez; Volume 25, Issue 2 (June, 2016) pp. 21-29

2015

In the Bookstores: Statistical Thinking for Non-Statisticians in Drug Regulation (Second Edition). Section editors: Alison McIntosh and Stephen Gilliver; Volume 24, Issue 4 (December, 2015) pp. 245-247 *(this article is a book review; it includes details about Chapter 19 of the book, which deals with various aspects of safety data analysis and the*

role of Data Monitoring Committees, including quantification of the benefit-risk balance for regulatory submissions, the importance of pharmacovigilance, and the use of proportional reporting ratios in evaluating safety signals)

Layperson summaries of clinical trial results: Useful resources in the vacuum of regulatory guidance. Claire L. Gillow; Volume 24, Issue 4 (December, 2015) pp. 205-209
(this article provides information on suitable lay safety language)

Medical writing for two audiences – The RMP public summary. Kerstin Prechtel, Stefanie Rechtsteiner; Volume 24, Issue 4 (December, 2015) pp. 200-204

'Safe', 'safety', and 'potential risk': Examples of euphemisms used by the pharma industry. Laura C. Collada Ali (Gained in Translation; Section editor: Laura C. Collada Ali); Volume 24; Issue 2 (June, 2015) pp. 101-104

The Webscout: Risk Management. Marc Briele (Section editor: Karin Eichele); Volume 24, Issue 2 (June, 2015) pp. 93-94

Using social media as the patient's voice in the benefit-risk assessment of drugs: Are we ready? Massoud Toussi, Lisa Chamberlain James, Sir Alasdair Breckenridge; Volume 24, Issue 2 (June, 2015) pp. 77-81

A shot at demystifying the risk management plan for medical writers. Sandra Götsch; Volume 24, Issue 2 (June, 2015) pp. 72-76

Pharmacovigilance medical writing: an evolving profession. Tiziana von Bruchhausen and Kerstin Prechtel; Volume 24, Issue 2 (June, 2015) pp. 66-71

The changing face of (benefit-)risk management. Lesley Wise; Volume 24, Issue 2 (June, 2015) pp. 62-65

Writing for a Public Audience. Wendy Kingdom (Medical Communications, Section editor: Lisa Chamberlain James); Volume 24, Issue 1 (March, 2015) pp. 43-45
(this article addresses the growing importance of writing for a lay audience and the requirement that companies nowadays face, namely to include a lay summary of safety concerns in the RMP and to provide lay summaries of clinical study results)

2014

Non-interventional Post-Authorisation Safety Studies (NI-PASS): A different type of report; Gregory Morley. Volume 23, Issue 4 (December, 2014) pp. 273-276

Strategic medical writing in the post-authorisation phase; Sarah J. Richardson. Volume 23 Issue 4 (December, 2014) pp. 267-272

Post-approval regulatory writing – How different is it from writing pre-approval documents; Sunil Modali. Volume 23, Issue 4 (December, 2014) pp. 262-266

Responding to concerns over the PSMF: inspectors offer key insights. Dakshayini Kulkarni; Volume 23, Issue 4 (December, 2014) pp. 259-261
(this article focuses on the feedback provided by the inspectors during their assessment of

the Pharmacovigilance System Master File [PMSF] with an emphasis on areas for improvement)

Adverse event reporting: a brief overview of MedDRA. Gregory Morley; Volume 23, Issue 2 (June, 2014) pp. 113-116

An overview of the Common Technical Document (CTD) regulatory dossier. Debbie Jordan; Volume 23, Issue 2 (June, 2014) pp. 101-105

The Investigator's Brochure: a multidisciplinary document. Douglas Fiebig; Volume 23, Issue 2 (June, 2014) pp. 96-100
(this article addresses how to approach the IB section: Effects in Human: summary of safety information)

Effective authoring of clinical study reports: a companion guide. Sam Hamilton; Volume 23, Issue 2 (June, 2014) pp. 86-92
(this article discusses requirements for clinical safety narratives compared with PV safety narratives)

A guide to pre-approval regulatory documents. Raquel Billiones; Volume 23, Issue 2 (June, 2014) pp. 84-85
(this article presents a broad overview of the whole range of documents to be prepared pre-approval, including those involving clinical safety aspects)

2013

No relevant article identified

2012

The MHRA perspective on the new pharmacovigilance legislation. Mick Foy; Volume 21, Issue 2 (June, 2012) pp. 128 – 130

Some considerations on the safety evaluation section of clinical study reports for studies with anticancer drugs. Vincente Alfaro; Volume 21, Issue 1 (March, 2012) pp. 23-25

News from the EMA published in MEW on PV and safety

2019

News from the EMA. Section editor: Anuradha Alahari; Volume 28, Issue 3 (September, 2019) pp. 79-82

News from the EMA. Section editor: Anuradha Alahari; Volume 28, Issue 2 (June, 2019) pp. 94-97

News from the EMA. Section editor: Anuradha Alahari; Volume 28, Issue 1 (March, 2019) pp. 78-81

2018

News from the EMA. Section editor: Anuradha Alahari; Volume 28, Issue 4 (December, 2018) pp. 60-63

News from the EMA. Section editor: Anuradha Alahari; Volume 28, Issue 3 (September, 2018) pp. 47-50

News from the EMA. Section editor: Anuradha Alahari; Volume 28, Issue 2 (June 2018) pp. 76-79

News from the EMA. Section editor: Anuradha Alahari; Volume 27, Issue 1 (March, 2018) pp. 68-72

2017

News from the EMA. Section editor: Anuradha Alahari; Volume 26, Issue 4 (December, 2017) pp. 52-54

News from the EMA. Section editor: Anuradha Alahari; Volume 26, Issue 1 (March, 2017) pp. 50-51

2016

News from the EMA. Section editor: Anuradha Alahari; Volume 25, Issue 4 (December, 2016) pp. 44-46

News from the EMA. Section editor: Anuradha Alahari; Volume 25, Issue 3 (September, 2016) pp. 55-57

News from the EMA. Section editor: Anuradha Alahari; Volume 25, Issue 2 (June, 2016) pp. 38-41

2015

News from the EMA. Section editor: Monika Benstetter; Volume 24, Issue 4 (December, 2015) pp. 236-239

News from the EMA. Section editor: Monika Benstetter; Volume 24, Issue 3 (September, 2015) pp. 145-147

News from the EMA. Section editor: Monika Benstetter; Volume 24, Issue 2 (June, 2015) pp. 86-90

News from the EMA. Section editor: Monika Benstetter; Volume 24, Issue 1 (March, 2015) pp. 30-33

Other Recent MEW Articles Relevant for PV (Safety) Writers

2019

Clinical trial disclosure landscape and awareness in Japan. Hiroko Ebina and Jocelyn Colquhoun; Volume 28, Issue 1 (March, 2019) pp. 74-77
(this article mentions clinical safety requirements in Japan)

The next medical device scandal: Medical device files – my personal view (Part 1).
Section editor: Beatrix Doerr; Volume 28, Issue 1 (March, 2019) pp. 86-89
(this article addresses changes in post-market surveillance and safety reporting for medical devices over the last 10 years)

Career opportunities in medical device writing: Employee and freelance perspectives; Sarah F. Choudhury and Gillian Pritchard; Volume 28, Issue 1 (March, 2019) pp. 46-50
(the article addresses the ways in which PV writing experience is beneficial for switching to medical device writing, for which safety/surveillance is also an important topic)

2018

Estimands – closing the gap between study design and analysis. Helen Bridge and Thomas M. Schindler; Volume 27, Issue 4 (December, 2018) pp. 52-56
(this article addresses the efficacy and safety information provided by estimand analysis)

Medical devices: Useful links for medical device writing. Section editor: Beatrix Doerr. Volume 28, Issue 3 (September, 2018) pp. 57
(this article mentions the sponsor's obligation to provide Periodic Safety Update Reports)

MDR and MEDDEV – What notified bodies are looking for in Clinical Evaluation Reports (CER). Itoro Udofia (Reports from the spring conference in Barcelona. Section editor: Amy Whereat); Volume 27, Issue 3 (Sep, 2018) pp. 38
(this article mentions the sponsor's obligation to provide Risk Management [and other post-approval safety] documentation)

2017

Introduction to the legal implications of medical writing. Joanne Flitcroft (Section editor: Lisa Chamberlain James); Volume 26, Issue 4 (December, 2017) pp. 67-68
(this article discusses the legal implications of defending product safety issues)

Nonclinical studies in the Russian Federation: Problems, regulatory norms, and harmonisation with international standards. Anna Buryakina and Natalie Merkulova; Volume 26, Issue 4 (December, 2017) pp. 33-37
(this article presents nonclinical safety requirements in the Russian Federation versus ICH requirements)

An introduction to little-known aspects of nonclinical regulatory writing. Alexander Nürnberg and Hélène Pierre; Volume 26, Issue 4 (December, 2017) pp. 9-19
(this article offers insight into the range of safety assessments in the nonclinical setting)

Preclinical research in drug development. Jennifer Honek; Volume 26, Issue 4 (December, 2017) pp. 5-8
(this article covers toxicity study aspects)

French breast implants, the Medical Device Regulation, and a theoretical case study. Claudia Frumento. Volume 26, Issue 2 (June, 2017) pp. 39-40
(this article addresses the need for patient and user safety in medical device development)

Medical devices in the disclosure era and the role of medical writers. Raquel Billiones. Volume 26, Issue 2 (June, 2017) pp. 32-34
(this article summarizes recent MDR updates in safety requirements for medical devices)

Medical Device Regulation: A necessary step towards more patient and user safety. Claudia Frumento; Volume 26, Issue 2 (June, 2017) pp. 25-28
(this article addresses the need for patient and user safety in medical device development)

New EU medical device regulations: Impact on the MedTech sector. Robert Behan, Mark Watson, and Abhay Pandit; Volume 26, Issue 2 (June, 2017) pp. 20-24
(this article presents how the need for better safety and quality requirements for medical devices will be better met in light of the updated regulatory framework in the EU)

Clinical Evaluation Reports from the medical writer's perspective! Gillian Pritchard; Volume 26, Issue 2 (June, 2017) pp. 14-19
(this article presents the objective of Clinical Evaluation Reports, i.e. to support the conformity of a medical device with the essential requirements and the safety performance required by the MDR)

Writing for medical devices compared to pharmaceuticals: An introduction. Beatrix Doerr, Sophia Whitman, and Steven Walker; Volume 26, Issue 2 (June, 2017) pp. 8-13
(this article presents differences and similarities between [writing in] the medical device industry and in the pharmaceutical industry, including in terms of safety requirements)