



Hier finden Sie eine Zusammenstellung der Veröffentlichungen von **Mitarbeiterinnen und Mitarbeitern** des BfArM aus dem Jahr 2019

## Originalarbeiten, referiert

Amare AT, Schubert KO, Tekola-Ayele F, Hsu YH, Sangkuhl K, Jenkins G, Whaley RM, Barman P, Batzler A, Altman RB, Arolt V, Brockmöller J, Chen CH, Domschke K, Hall-Flavin DK, Hong CJ, Illi A, Ji Y, Kampman O, Kinoshita T, Leinonen E, Liou YJ, Mushiroda T, Nonen S, Skime MK, Wang L, Kato M, Liu YL, Praphanphoj V, **Stingl JC**, Bobo WV, Tsai SJ, Kubo M, Klein TE, Weinshilboum RM, Biernacka JM, Baune BT (2019) The association of obesity and coronary artery disease genes with response to SSRIs treatment in major depression.  
*J Neural Transm* 126(1):35-45

Andlauer TFM, Guzman-Parra J, Streit F, Strohmaier J, Gonzalez MJ, Gil Flores S, Cabaleiro Fabeiro FJ, Del Rio Noriega F, Perez FP, Haro Gonzalez J, Orozco Diaz G, de Diego-Otero Y, Moreno-Küstner B, Auburger G, Degenhardt F, Heilmann-Heimbach S, Herms S, Hoffmann P, Frank J, Foo JC, Treutlein J, Witt SH, Cichon S, Kogevinas M, **Bipolar Disorder Working Group of the Psychiatric Genomics Consortium, Steffens M**, Major Depressive Disorder Working Group of the Psychiatric Genoms Consortium, Rivas F, Mayoral F, Müller-Myhsok B, Forstner AJ, Nöthen MM, Rietschel M (2019) Bipolar multiplex families have an increased burden of common risk variants for psychiatric disorders.  
*Mol Psychiatry* Epub 11.11.2019 (doi: 10.1038/s41380-019-0558-2)

**Barth U** (2019) Schwerwiegende unerwünschte Ereignisse in klinischen Prüfungen mit TAVR und SAVR.  
*Herz* 44(6):526-533

**Benda N, Haenisch B** (2019) Enrichment design using placebo non-responders.  
*Pharm Stat* in press

Coch C, Viviani R, **Breitfeld J**, Münzer K, Dassler-Plenker J, Holdenrieder S, Coenen M, **Steffens M**, Müller M, Hartmann G, **Stingl JC** (2019) Interferon-beta-induced changes in neuroimaging phenotypes of appetitive motivation and reactivity to emotional salience.  
*Neuroimage Clin* 24:102020

**Cremer-Schaeffer P, Schmidt-Wolf G, Broich K** (2019) Cannabisarzneimittel in der Schmerztherapie: Zwischenauswertung der Cannabisbegleiterhebung hinsichtlich der primär behandelten Symptomatik Schmerz.  
*Schmerz* 33(5):415-423, <https://doi.org/10.1007/s00482-019-00399-z>

Dawed AY, Zhou K, van Leeuwen N, Mahajan A, Robertson N, Koivula R, Elders PJM, Rauh SP, Jones AG, Holl RW, **Stingl JC**, Franks PW, McCarthy MI, t Hart LM, Pearson ER (2019) Variation in the Plasma Membrane Monoamine Transporter (PMAT) (Encoded by *SLC29A4*) and Organic Cation Transporter 1 (OCT1) (Encoded by *SLC22A1*) and Gastrointestinal Intolerance to Metformin in Type 2 Diabetes: An IMI DIRECT Study.  
*Diabetes Care* 42(6):1027-1033

Hampel H, Vergallo A, Afshar M, Akman-Anderson L, Arenas J, **Benda N**, Batrla R, **Broich K**, Caraci F, Cuello AC, Emanuele E, **Haberkamp M**, Kiddie SJ, Lucia A, Mapstone M, Verdooner SR, Woodcock J, Lista S (2019) Blood-based systems biology biomarkers for next-generation clinical trials in Alzheimer's disease.  
*Dialogues Clin Neurosci* 21(2):177-191

**Huber C, Benda N**, Friede T (2019) A comparison of subgroup identification methods in clinical drug development: Simulation study and regulatory considerations.  
*Pharm Stat* 18(5):600-626

**Hübner T, Steffens M**, Linder R, **Fracowiak J**, Langner D, Garling M, Heilmann T, Roethlein C, Gomm W, **Haenisch B**, **Stingl JC** (2019) Protocol of the cohort study EMPAR: Influence of Metabolic Profiles on the Safety of Drug Therapy in Routine Care in Germany.  
*BMJ Open* in press

Igl BW, Bitsch A, Bringezu F, Chang S, Dammann M, **Frötschl R**, Harm V, Kellner R, Krzykalla V, Lott J, Nern M, Pfuhler S, Queisser N, Schulz M, Sutter A, Vaas L, Vonk R, Zellner D, Ziemann C (2019) The rat bone marrow micronucleus test: Statistical considerations on historical negative control data.  
*Regul Toxicol Pharmacol* 102(3):13-22

Jackson SJ, Authier S, **Brohmann H**, Goody SMG, Jones D, Prior H, Rosch A, Traebert M, Tse K, Valentin JP, Milne A (2019) Neurofunctional test batteries in safety pharmacology – Current and emerging considerations for the drug development process.  
*J Pharmacol Toxicol Methods* 100:106602

**Just K, Dormann H, Böhme M, Schurig M, Schneider K, Steffens M, Dunow S**, Plank-Kiegele B, Ettrich K, Seufferlein T, Gräff I, Igel S, Schricker S, Jaeger S, Schwab M, **Stingl JC** (2019) Personalising drug safety – results from the multi-centre prospective observational study on adverse drug reactions in emergency departments (ADRED).  
*Eur J Clin Pharmacol* in press

Karas Kuzelicki N, Prodan Zitnik I, Gurwitz D, Llerena A, Cascorbi I, Siest S, Simmaco M, Ansari M, Pazzaglia M, Di Resta C, Brandslund I, Schwab M, Vermeersch P, Lunshof JE, Dedoussis G, Flordellis CS, Fuhr U, **Stingl JC**, van Schaik RH, Manolopoulos VG, Marc J & the Pharmacogenomics Working Group (PGxEWG) (2019) on behalf of the European Society of Pharmacogenomics and Personalized Therapy (ESPT): Pharmacogenomics education in medical and pharmacy schools: conclusions of a global survey.

*Pharmacogenomics* 20(9):643-657

**Knöss W, Wiesner J** (2019) The Globalization of Traditional Medicines: Perspectives Related to the European Union Regulatory Environment.

*Engineering* 5(1):22-31

Kraus L, Seitz NN, Schulte B, **Cremer-Schaeffer P**, Braun B, Verthein U, Pfeiffer-Gerschel T (2019) Estimation of the Number of People With Opioid Addiction in Germany.  
*Dtsch Arztebl Int* 116(9):137-143

**Lundt A, Henseler C, Wormuth C, Soos J, Seidel R, Müller R, Arshaad MI, Broich K, Hescheler J, Sachinidis A, Ehninger D, Papazoglou A, Weiergräber M** (2019) Gender specific click and tone burst evoked ABR datasets from mice lacking the Cav3.2 T-type voltage-gated calcium channel.  
*BMC Res Notes* 12(1):157

**Lundt A, Seidel R, Soos J, Henseler C, Müller R, Bakki M, Arshaad MI, Ehninger D, Hescheler J, Sachinidis A, Broich K, Wormuth C, Papazoglou A, Weiergräber M** (2019) Cav3.2 T-Type Calcium Channels Are Physiologically Mandatory for the Auditory System.  
*Neuroscience* 409:81-100

**Lundt A, Soos J, Henseler C, Arshaad MI, Müller R, Ehninger D, Hescheler J, Sachinidis A, Broich K, Wormuth C, Papazoglou A, Weiergräber M** (2019) Data Acquisition and Analysis In Brainstem Evoked Response Audiometry In Mice.  
*J Vis Exp* 147:e59200, doi:10.3791/59200

**Lundt A, Soos J, Seidel R, Henseler C, Müller R, Raj Ginde V, Arshaad MI, Ehninger D, Hescheler J, Sachinidis A, Broich K, Wormuth C, Papazoglou A, Weiergräber M** (2019) Functional implications of Cav 2.3 R-type voltage-gated calcium channels in the murine auditory system – novel vistas from brainstem-evoked response audiometry.  
*Eur J Neurosci* Epub ahead of print 11.10.2019

Nerius M, **Haenisch B**, Gomm W, Doblhammer G, Schneider A (2019) Glucocorticoid Therapy is Associated with a Lower Risk of Dementia.  
*J Alzheimers Dis* Epub ahead of print



Paulzen M, **Stingl JC**, Augustin M, Sassmannshausen H, Franz C, Gründer G, Schoretsanitis G (2019) Comprehensive Measurements of Intrauterine and Postnatal Exposure to Lamotrigine. *Clin Pharmacokinet* 58(4):535-543

**Sachs B, Dubrall D, Fischer-Barth W, Schmid M, Stingl JC** (2019) Drug-induced anaphylactic reactions in children: A retrospective analysis of 159 validated spontaneous reports. *Pharmacoepidemiol Drug Saf* 28(3):377-388

**Schmidt-Wolf G, Cremer-Schaeffer P** (2019) Begleiterhebung zur Anwendung von Cannabis-arzneimitteln in Deutschland - Zwischenauswertung. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 62(7):845-854

Stahl EA, Breen G, Forstner AJ, McQuillin A, Ripke S, Trubetskoy V, Mattheisen M, ..., **Steffens M**, ..., Bipolar Disorder Working Group of the Psychiatric Genomics Consortium (2019) Genome-wide association study identifies 30 loci associated with bipolar disorder. *Nat Genet* 51(5):793-803

Stamer UM, Schmutz M, Wen T, Banz V, Lippuner C, Zhang L, **Steffens M**, Stüber F (2019) A serotonin transporter polymorphism is associated with postoperative nausea and vomiting: An observational study in two different patient cohorts. *Eur J Anaesthesiol* 36(8):566-574

Uciteli A, Kropf S, Weiland T, Meese S, Graef K, Rohrer S, Schurr MO, Bartussek W, Goller C, Blohm P, **Seidel R, Bayer C, Kernenbach M, Pfeiffer K, Lauer W**, Meyer JU, Witte M, Herre H (2019) Ontology-based specification and generation of search queries for post-market surveillance. *J Biomed Semantics* 10(1):9

Unkel S, Amiri M, **Benda N**, Beyersmann J, Knoerzer D, Kupas K, Langer F, Leverkus F, Loos A, Ose C, Proctor T, Schmoor C, Schwenke C, Skipka G, Unnebrink K, Voss F, Friede T (2019) On estimands and the analysis of adverse events in the presence of varying follow-up times within the benefit assessment of therapies. *Pharm Stat* 18(2):166-183

Urlaub J, **Norwig J**, Schollmayer C, Holzgrabe U (2019)  $^1\text{H}$  NMR analytical characterization of mineral oil hydrocarbons (PARAFFINS) for pharmaceutical use. *J Pharm Biomed Anal* 169:41-48

van der Laan JW, van Malderen K, de Jager N, Duarte D, Egger GF, Lavergne F, Roque CG, Vieira I, **Wiesner L**, Carleer J (2019) Evaluation of Juvenile Animal Studies for Pediatric CNS-Targeted Compounds: A Regulatory Perspective. *Int J Toxicol* 38(6):456-475



## **Letter/Correspondence**

Herold R, Camarero J, Melchiorri D, Sebris Z, **Enzmann H**, Pignatti F (2019) Revocation of the conditional marketing authorisation of a cancer medicine: The olaratumab experience [Letter to the Editor].

*Eur J Cancer* 123:25-27

Urlaub J, **Norwig J**, Schollmayer C, Holzgrabe U (2019) Reply to "Requirements for accurate <sup>1</sup>H NMR quantification of mineral oil hydrocarbons (paraffins) for pharmaceutical or cosmetic use".

*J Pharm Biomed Anal* 171:235-237

## **Reviews, referiert**

Babiloni C, Blinowska K, Bonanni L, Cichocki A, De Haan W, Del Percio C, Dubois B, Escudero J, Fernandez A, Frisoni G, Guntokin B, Hajos M, Hampel H, Ifeachor E, Kilborn K, Kumar S, Johnsen K, Johannsson M, Jeong J, LeBeau F, Lizio R, Lopes da Silva F, Maestu F, McGeown WJ, McKeith I, Moretti DV, Nobili F, Olichney J, Onofrj M, Palop JJ, Rowan M, Stocchi F, Struzik ZM, Tanila H, Teipel S, Taylor JP, **Weiergräber M**, Yener G, Young-Pearse T, Dringenburg WH, Randall F (2019) What electrophysiology tells us about Alzheimer's disease: a window into the synchronization and connectivity of brain neurons.

*Neurobiol Aging* 85:58-73

**Benda N** (2019) Book Review: Quantitative decisions in drug development. Chuang-Stein, Christy and Kirby, Simon (2017). Cham (CH): Springer Series in Pharmaceutical Statistics. 248 pages, ISBN: 978-3-319-46075-8 (Hardback).

*Biom J* 61(4):1090-1091

**Buchholzer ML, Kirch M, Kirchner C, Knöss W** (2019) Toxicological assessment compilation of selected examples of raw materials for homeopathic medicinal products.

*Regul Toxicol Pharmacol* 103:253-273

Chen ML, Blume H, Beuerle G, Mehta M, **Potthast H, Brandt A**, Schug BS, Ducharme M, Endrenyi L, Gallicano K, Schuirmann D, Welink J (2019) Summary report of second EUFEPS/AAPS conference on global harmonization in bioequivalence.

*Eur J Pharm Sci* 127:24-28

Cheung A, Neuschwander-Tetri BA, Kleiner DE, **Schabel E**, Rinella M, Harrison S, Ratziu V, Sanyal AJ, Loomba R, Jeannin Megnien S, Torstenson R, Miller V (2019) Defining Improvement in Nonalcoholic Steatohepatitis for Treatment Trial Endpoints: Recommendations From the Liver Forum.

*Hepatology* 70(5):1841-1855

Crane C, Santos GML, Fernandes EAF, Simon C, Tam A, Triana DG, **Potthast H**, Kuribayashi R, Okada Y, Myozenzo A, Calderon IO, Rodriguez Z, Jones B, Park SA, Eum SY, Rodrigues C, Van Oudsthoorn J, Nolting A, Walther C, Roost MS, Hung WY, Braddy AC, Garcia-Arieta A (2019) The Requirements for Additional Strength Biowaivers for Immediate Release Solid Oral Dosage Forms in International Pharmaceutical Regulators Programme Participating Regulators and Organisations: Differences and Commonalities.

*J Pharm Pharm Sci* 22(1):486-500

**Cremer-Schaeffer P, Knöss W** (2019) Cannabis zu medizinischen Zwecken – Das Gesetz vom März 2017 und seine Vorgeschichte.

*Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 62(7):801-805

**Cremer-Schaeffer P, Knöss W, Broich K** (2019) Cannabis als Medizin: Auswirkungen des Gesetzes vom 6. März 2017 auf die Ärzteschaft.

*Schmerz* 33(5):378-383, doi: 10.1007/s00482-019-0387-x

Eichler HG, Bloechl-Daum B, **Broich K**, Kyrle PA, Oderkirk J, Rasi G, Santos Ivo R, Schuurman A, Senderovitz T, Slawomirski L, Wenzl M, Paris V (2019) Data Rich, Information Poor: Can We Use Electronic Health Records to Create a Learning Healthcare System for Pharmaceuticals?

*Clin Pharmacol Ther* 105(4):912-922

Eichler H-G, Koenig F, Arlett P, **Enzmann H**, Humphreys A, Pétavy F, Schwarzer-Daum B, Sepodes B, Vamvakas S, Rasi G (2019) Are Novel, Nonrandomized Analytic Methods Fit for Decision Making? The Need for Prospective, Controlled, and Transparent Validation.

*Clin Pharmacol Ther* published online 01.10.2019

<https://ascpt.onlinelibrary.wiley.com/doi/abs/10.1002/cpt.1638>

Gini R, Fournie X, Dolk H, Kurz X, Verpillat P, Simondon F, **Strassmann V**, Apostolidis K, Goedecke T (2019) The ENCePP Code of Conduct: A best practise for scientific independence and transparency in noninterventional postauthorisation studies.

*Pharmacoepidemiol Drug Saf* 28(4):422-433

Graf von Kielmansegg S, **Benda N**, Grass G, **Sudhop T** (2019) Die Rolle von Ethikkommissionen bei der Bewertung klinischer Arzneimittelprüfungen.

*Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 62(6):706-712

Halamoda-Kenzaoui B, Baconnier S, Bastogne T, Bazile D, Boisseau P, Borchard G, Borgos SE, Calzolai L, Cederbrant K, Di Felice G, Di Francesco T, Dobrovolskaia MA, Gaspar R, Gracia B, Hackley VA, Leyens L, Liptrott N, Park M, Patri A, Roebben G, Roesslein M, **Thürmer R**, Urban P, Zuang V, Bremer-Hoffmann S (2019) Bridging communities in the field of nanomedicine. *Regul Toxicol Pharmacol* 106:187–196

Just KS, Turner RM, Dolzan V, Cecchin E, Swen JJ, Gurwitz D, Stingl JC (2019) Educating the Next Generation of Pharmacogenomics Experts: Global Educational Needs and Concepts. *Clin Pharmacol Ther* 106(2):313–316

Knöss W, van de Velde M, Sandvos C, Cremer-Schaeffer P (2019) Key elements of legal environments for medical use of cannabis in different countries. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 62(7):855–860

Laroche C, Annys E, Bender H, Botelho D, Botham P, Brendler-Schwaab S, Clayton R, Corvaro M, Dal Negro G, Delannois F, Dent M, Desaintes C, Desprez B, Dhalluin S, Hartmann A, Hoffmann-Doerr S, Hubesch B, Irizar A, Manou I, Müller BP, Nadzialek S, Prieto P, Rasenberg M, Roggeband R, Rowan TG, Schutte K, van de Water B, Westmoreland C, Whelan M, Wilschut A, Zvonimir Z, Cronin MTD (2019) Finding synergies for the 3Rs – Repeated Dose Toxicity testing: Report from an EPAA Partners' Forum.

*Regul Toxicol Pharmacol* 108:104470, doi: 10.1016/j.yrtph.2019.104470

Lenic I, Blake K, Garcia-Arieta A, Potthast H, Welink J (2019) Overview of the European Medicines Agency's Experience With Biowaivers in Centralized Applications. *Clin Transl Sci* 12(5):490–496

Li HH, Yauk CL, Chen R, Hyduke DR, Williams A, Frötschl R, Ellinger-Ziegelbauer H, Pettit S, Aubrecht J, Fornace AJ (2019) TGx-DDI, a Transcriptomic Biomarker for Genotoxicity Hazard Assessment of Pharmaceuticals and Environmental Chemicals. *Frontiers in Big Data* 2(36)

Lynch AM, Eastmond D, Elhajouji A, Frötschl R, Kirsch-Volders M, Marchetti F, Masumura K, Pacchierotti F, Schuler M, Tweats D (2019) Targets and mechanisms of chemically induced aneuploidy. Part 1 of the report of the 2017 IWGT workgroup on assessing the risk of aneugens for carcinogenesis and hereditary diseases. *Mutat Res* 847:403025

Manns D, Norwig J, Reh K (2019) Cannabis für medizinische Zwecke: Entwicklung von Arzneibuchmonographien als Qualitätsstandard. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 62(7):806–810



Pacchierotti F, Masumura K, Eastmond DA, Elhajouji A, **Frötschl R**, Kirsch-Volders M, Lynch A, Schuler M, Tweats D, Marchetti F (2019) Chemically induced aneuploidy in germ cells. Part II of the report of the 2017 IWGT workgroup on assessing the risk of aneugens for carcinogenesis and hereditary diseases.

*Mutat Res* 848:403023

Prien T, **Brinker A**, Pfeiffer K, Van Aken HK (2019) Equipment Problems. Preventable Anesthetic Deaths: Is "PaF" the Magic Dragon?  
*Anesth Analg* 129(5):1439-1441

**Sudhop T**, Brun NC, **Riedel C**, Rosso A, **Broich K**, Senderovitz T (2019) Master protocols in clinical trials: a universal Swiss Army knife?  
*Lancet Oncology* 20(6):e336-e342

Tweats D, Eastmond DA, Lynch AM, Elhajouji A, **Frötschl R**, Kirsch-Volders M, Marchetti F, Masumura K, Pacchierotti F, Schuler M (2019) Role of aneuploidy in the carcinogenic process: Part 3 of the report of the 2017 IWGT workgroup on assessing the risk of aneugens for carcinogenesis and hereditary diseases.

*Mutat Res* 847:403032

Unterecker S, Hefner G, Baumann P, Gründer G, Bergemann N, Clement HW, Conca A, Deckert J, Domschke K, Eckermann G, Egberts K, Gerlach M, **Greiner C**, Haen E, Havemann-Reinecke U, Helmer R, Janssen G, Jaquenoud E, Laux G, Messer T, Mössner R, Müller MJ, Paulzen M, Pfuhlmann B, Riederer P, Saria A, Schoppek B, Schoretsanitis G, Schwarz M, Gracia MS, Stegmann B, Steimer W, **Stingl JC**, Uhr M, Ulrich S, Waschgler R, Zernig G, Zurek G, Hiemke C (2019) Therapeutisches Drug-Monitoring in der Neuropsychopharmakologie – Zusammenfassung der Konsensusleitlinien 2017 der TDM-Arbeitsgruppe der AGNP.  
*Nervenarzt* 90(5):463-471

**Weiergräber M**, **Broich K** (2019) Neuroenhancement – Hirndoping.  
*Psychopharmakotherapie* 26(3):117-127

**Weise M** (2019) From bioequivalence to biosimilars: How much do regulators dare?  
*Z Evid Fortbild Qual Gesundhwes* 140:58-62

Wolff-Holz E, Tiitso K, Vleminckx C, **Weise M** (2019) Evolution of the EU Biosimilar Framework: Past and Future.  
*BioDrugs* 33(6):621-634

## Sonstige Publikationen

**Brinker A, Pfeiffer K, Lange K, Stößlein E, Zündorf J, Lauer W, Broich K** (2019) Anästhesie: Zwischenfälle vermeiden.  
*Dtsch Arztebl* 116(33-34):A1500-A1501

**Cremer-Schaeffer P, Häuser W** (2019) Cannabis [Editorial].  
*Schmerz* 33(5):375-377, doi: 10.1007/s00482-019-00396-2

**Cremer-Schaeffer P, Knöss W** (2019) Cannabis für medizinische Zwecke: Dynamische Rahmenbedingungen – sachgerechte Information [Editorial].  
*Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 62(7):799-800

**Diesinger C, Seifert K, Kayser C, Lütkehermölle W** (2019) Methotrexat und das Risiko für Medikationsfehler.  
*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 4:4-13

**Dimitrova G** (2019) Direct Healthcare Professional Communication (DHPC) als Teil der Risikokommunikation resultierend aus europäischen Risikobewertungsverfahren und ihre nationale Umsetzung in Deutschland als Rote-Hand-Brief.  
*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 3:21-30

Eichler HG, **Enzmann H**, Rasi G (2019) Added therapeutic benefit and drug licensing [comment].  
*Nat Rev Drug Discov* 18(4), doi:10.1038/d41573-019-00068-x

**Frizler M** (2019) Thyreostatische Behandlung des Morbus Basedow während der Schwangerschaft.  
*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 4:14-28

**Gassen J, Leutenantsmeyer T, Schaefer J, Palissa H** (2019) Behördlich genehmigtes Schulungsmaterial – eine Bestandsaufnahme.  
*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 1:28-36

**Haberkamp M, Moseley J, Athanasiou D, de Andres-Trelles F, Elferink A, Rosa MM, Magrelli A** (2019) European regulators' views on a wearable-derived performance measurement of ambulation for Duchenne muscular dystrophy regulatory trials [short communication].  
*Neuromuscul Disord* 29(7):514-516

Held T, **Hichert V** (2019) Panzytopenie durch Fingolimod: Hypothese eines neuen Mechanismus.  
*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 2:11-14



**Katic J, Meier T** (2019) Domperidon – Wirksamkeit der Sicherheitsmaßnahmen zur Minimierung von kardialen Risiken.

*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 3:13-20

**Kommas E, Lex D, Huber M, Paeschke N** (2019) Verdachtsfälle melden.

*Dtsch Apoth Ztg* 37:44

**Löbker W, Lauer W, Broich K** (2019) Wer entscheidet – Arzt oder App? Die Sicht des BfArM.

*Kompendium Diabetes* 14(1)

**Meier T** (2019) Natrium-Glukose-Co-Transporter-2(SGLT2)-Hemmer und das Auftreten einer Fournier-Gangrän.

*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 2:4-10

O'Connor DJ, Sheean ME, Hofer MP, Tsigkos S, Mariz S, Fregonese L, Larsson K, Hivert V, Westermark K, **Naumann-Winter F**, Stoyanova-Beninska V, Barisic I, Capovilla G, Magrelli A, Sepodes B (2019) Defining orphan conditions in the context of the European orphan regulation: challenges and evolution [comment].

*Nat Rev Drug Discov* 18(7):479-480

**Römisch C, Knöss W** (2019) Pharmakovigilanz pflanzlicher Arzneimittel – Stellenwert der Spontanberichterstattung.

*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 1:11-18

**Sachs B, Bücker B, Bick N** (2019) Depressionen und Suizidalität unter Anwendung hormonaler Kontrazeptiva.

*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 1:4-10

**Sachs B, Frizler M** (2019) Direkte orale Antikoagulanzien: Keine Anwendung bei Patienten mit Antiphospholipidsyndrom.

*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 3:4-12

Said A, Ganso M, Parrau N, Schulz M, **Kayser C** (2019) Medikationsfehler in der Praxis: Die Bedeutung von Look- und Soundalikes als Mitursache von Medikationsfehlern.

*Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 2:24-36

Sasaki JC, Allemang A, Bryce SM, Custer L, Dearfield KL, Dietz Y, Elhajouji A, Escobar PA, Fornace AJ Jr., **Frötschl R**, Galloway S, Hemmann U, Hendriks G, Li HH, Luijten M, Ouedraogo G, Peel L, Pfuhler S, Roberts DJ, Thybaud V, van Benthem J, Yauk CL, Schuler M (2019) Application of the adverse outcome pathway framework to genotoxic modes of action [commentary].

*Environ Mol Mutagen* Epub ahead of print 11.10.2019



Schuessler-Lenz M, **Enzmann H**, Vamvakas S (2019) Regulators' Advice Can Make a Difference: European Medicines Agency Approval of Zynteglo for Beta Thalassemia [commentary]. *Clin Pharmacol Ther* Epub ahead of print 08.11.2019

**Steffens M, Stingl JC, Haenisch B**, Linder R (2019) Vorstellung der Versorgungsstudie EMPAR. *Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI* 4:36-39

Vos MB, Dimick-Santos L, Mehta R, Omokaro SO, Taminiau J, **Schabel E**, Kleiner DE, Szitanyi P, Socha P, Schwimmer JB, Noviello S, Silberg DG, Torstenson R, Miller V, Lavine JE (2019) Factors to Consider in Development of Drugs for Pediatric Nonalcoholic Fatty Liver Disease [commentary]. *Gastroenterology* 157(6):1448-1456 e1

Wolff-Holz E, Müller-Berghaus J, **Weise M** (2019) Biosimilars in der Onkologie (Teil 1): Dank strenger Regulierung keine zweite Wahl. *Dtsch Arztebl Supplement: Perspektiven der Onkologie* 116(35-36)

Wolff-Holz E, Müller-Berghaus J, **Weise M** (2019) Biosimilars in der Onkologie (Teil 2): Wie man die Biosimilarität wissenschaftlich bestätigt.

*Dtsch Arztebl Supplement: Perspektiven der Onkologie* 116(46)

Zoller R, **Lange K, Nowak M, Lauer W** (2019) Alles gleichzeitig und trotzdem gut? (Teil 1). *intensiv* 27(2):77-79

Zoller R, **Lange K, Nowak M, Lauer W** (2019) Alles gleichzeitig und trotzdem gut? (Teil 2). *intensiv* 27(3):127-131

## **Bücher/Buchbeiträge**

**Enzmann H, Benda N, Meyer R, Scholl C, Stingl J, Broich K** (2019) Companion Diagnostics and Biomarker Tests in the European Medicines Agency's Assessment of Medicinal Products. In: Jorgensen JT (Hrsg) Companion and Complementary Diagnostics – From Biomarker Discovery to Clinical Implementation. Elsevier Academic Press, 319-333

**Thürmer R** (2019) Regulatory Perspective on Synthetic Peptides in Europe. In: Srivastava V (Hrsg) Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls. Royal Society of Chemistry, Cambridge, UK, 31-68

Wu L, Raw A, **Knöss W**, Smith M, Zhang W, Bedi Y, Gray E, Mulloy B (2019) Regulatory Landscapes for Approval of Naturally-Derived Complex Mixture Drugs – The EU Regulatory Framework for Herbal Medicinal Products and Traditional Herbal Medicinal Products. In: Sasisekharan R, Lee SL, Rosenberg A, Walker LA (Hrsg) The Science and Regulations of Naturally Derived Complex Drugs. AAPS Advances in the Pharmaceutical Sciences Series. Springer International Publishing, Cham, 17-44