# Postmarket Safety Outcomes for New Molecular Entity (NME) Drugs Approved by the Food and Drug Administration Between 2002 and 2014

DOI: 10.1002/cpt.944
Clinical Pharmacology and Therapeutics, 2018, 104, 390-400.

| # | Paper | IF | Citations |
|---|---|---|---|
| 27 | Evolving Landscape of US Food and Drug Administration Drug Approval in the Era of Precision Oncology: Finding the Right Balance Between Access and Safety. *Journal of Clinical Oncology*, **2018**, 36, 1773-1776 | 2.2 | 2 |
| 26 | Expediting drug development for serious illness: Trade-offs between patient access and certainty. *Clinical Trials*, **2018**, 15, 230-234 | 2.2 | 10 |
| 25 | The US Food and Drug Administration's expedited approval programs: Addressing premarket flexibility with enhanced postmarket evidence generation. *Clinical Trials*, **2018**, 15, 243-246 | 2.2 | 9 |
| 24 | Risk Management. **2019**, 581-616 | | |
| 23 | The Supreme Court's Latest Ruling on Drug Liability and its Implications for Future Failure-to-Warn Litigation. *Journal of Law, Medicine and Ethics*, **2019**, 47, 783-787 | 1.2 | |
| 22 | The Role of Pharmacoepidemiology in the Healthcare System and Academia. **2019**, 81-97 | | |
| 21 | An evaluation of statistical approaches to postmarketing surveillance. *Statistics in Medicine*, **2020**, 39, 845-874 | 2.3 | 7 |
| 20 | Towards Automating Adverse Event Review: A Prediction Model for Case Report Utility. *Drug Safety*, **2020**, 43, 329-338 | 5.1 | 8 |
| 19 | Characteristics on Drug Safety Measures in Japan Stratified by System Organ Classes and Therapeutic Categories in Relation to the Approval Date. *Therapeutic Innovation and Regulatory Science*, **2020**, 54, 1534-1540 | 1.2 | |
| 18 | FDA postmarketing safety labeling changes: What have we learned since 2010 about impacts on prescribing rates, drug utilization, and treatment outcomes. *Pharmacoepidemiology and Drug Safety* , **2020**, 29, 1022-1029 | 2.6 | 2 |
| 17 | Postmarketing Safety-Related Regulatory Actions for New Therapeutic Biologics Approved in the United States 2002-2014: Similarities and Differences With New Molecular Entities. *Clinical Pharmacology and Therapeutics*, **2020**, 108, 1243-1253 | 6.1 | 7 |
| 16 | The Biotechnology Sector: Therapeutics. **2020**, 89-302 | | 0 |
| 15 | Do current radical innovation measures actually measure radical drug innovation?. *Scientometrics*, **2021**, 126, 1049-1078 | 3 | 3 |
| 14 | A New Era in Pharmacovigilance: Toward Real-World Data and Digital Monitoring. *Clinical Pharmacology and Therapeutics*, **2021**, 109, 1197-1202 | 6.1 | 8 |
| 13 | Quantifying the severity of adverse drug reactions using social media. | | 0 |
| 12 | Comprehensive evaluation of post-approval regulatory actions during the drug lifecycle - a focus on benefits and risks. *Expert Opinion on Drug Safety*, **2021**, 20, 1433-1442 | 4.1 | 0 |
| 11 | The Impact of Variability in Patient Exposure During Premarket Clinical Development on Postmarket Safety Outcomes. *Clinical Pharmacology and Therapeutics*, **2021**, 110, 1512-1525 | 6.1 | 0 |

| | | | |
|---|---|---|---|
| 10 | The Use of Real-World Data to Assess the Impact of Safety-Related Regulatory Interventions. *Clinical Pharmacology and Therapeutics*, **2021**, 111, 98 | 6.1 | 0 |
| 9 | Quantifying the Severity of Adverse Drug Reactions Using Social Media: Network Analysis. *Journal of Medical Internet Research*, **2021**, 23, e27714 | 7.6 | 0 |
| 8 | Clinical analysis of adverse drug reactions and pharmacovigilance. **2022**, 499-517 | | |
| 7 | Postmarketing safety of orphan drugs: a longitudinal analysis of the US Food and Drug Administration database between 1999 and 2018.. *Orphanet Journal of Rare Diseases*, **2022**, 17, 3 | 4.2 | |
| 6 | Sources of Evidence Triggering and Supporting Safety-Related Labeling Changes: A 10-Year Longitudinal Assessment of 22 New Molecular Entities Approved in 2008 by the US Food and Drug Administration.. *Drug Safety*, **2022**, | 5.1 | 1 |
| 5 | "Artificial Intelligence" for Pharmacovigilance: Ready for Prime Time?. *Drug Safety*, **2022**, 45, 429-438 | 5.1 | 0 |
| 4 | Trends in the Quality of Evidence Supporting FDA Drug Approvals: Results from a Literature Review. *Journal of Health Politics, Policy and Law*, **2022**, | 2.6 | 0 |
| 3 | Association of expedited review programmes with postmarketing safety events of new drugs approved by the US food and drug administration between 2007 and 2017. **2022**, 12, e058843 | | |
| 2 | On the use of the likelihood ratio test methodology in pharmacovigilance. | | 0 |
| 1 | How do safety warnings on medicines affect prescribing?. 1-5 | | 0 |