

Hubert G M Leufkens

List of Publications by Year in descending order

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95
papers

2,005
citations

318942

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355658

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all docs

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docs citations

95
times ranked

2785
citing authors

#	ARTICLE	IF	CITATIONS
1	Building HTA insights into the drug development plan: Current approaches to seeking early scientific advice from HTA agencies. <i>Drug Discovery Today</i> , 2022, 27, 347-353.	3.2	6
2	Unmet Medical Need as a Driver for Pharmaceutical Sciences – A Survey Among Scientists. <i>Journal of Pharmaceutical Sciences</i> , 2022, 111, 1318-1324.	1.6	6
3	Pre-approval and post-approval availability of evidence and clinical benefit of conditionally approved cancer drugs in Europe: A comparison with standard approved cancer drugs. <i>British Journal of Clinical Pharmacology</i> , 2022, 88, 2169-2179.	1.1	5
4	Addressing uncertainty in relative effectiveness assessments by HTA organizations. <i>International Journal of Technology Assessment in Health Care</i> , 2022, 38, e17.	0.2	3
5	Key Considerations in the Health Technology Assessment of Advanced Therapy Medicinal Products in Scotland, The Netherlands, and England. <i>Value in Health</i> , 2022, 25, 390-399.	0.1	8
6	Market access to new anticancer medicines for children and adolescents with cancer in Europe. <i>European Journal of Cancer</i> , 2022, 165, 146-153.	1.3	9
7	The impact of FDA and EMA regulatory decision-making process on the access to CFTR modulators for the treatment of cystic fibrosis. <i>Orphanet Journal of Rare Diseases</i> , 2022, 17, 188.	1.2	24
8	Regulatory Safety Learning Driven by the Mechanism of Action: The Case of TNF- α Inhibitors. <i>Clinical Pharmacology and Therapeutics</i> , 2021, 110, 123-131.	2.3	4
9	Estimation of manufacturing development costs of cell-based therapies: a feasibility study. <i>Cytotherapy</i> , 2021, 23, 730-739.	0.3	12
10	Regulatory density as a means to refine current regulatory approaches for increasingly complex medicines. <i>Drug Discovery Today</i> , 2021, 26, 2221-2225.	3.2	2
11	Associations between uncertainties identified by the European Medicines Agency and national decision making on reimbursement by HTA agencies. <i>Clinical and Translational Science</i> , 2021, 14, 1566-1577.	1.5	10
12	Early Cost-Effectiveness of Onasemnogene Apeparovect-xioi (Zolgensma) and Nusinersen (Spinraza) Treatment for Spinal Muscular Atrophy I in The Netherlands With Relapse Scenarios. <i>Value in Health</i> , 2021, 24, 759-769.	0.1	24
13	Comprehensive evaluation of post-approval regulatory actions during the drug lifecycle – a focus on benefits and risks. <i>Expert Opinion on Drug Safety</i> , 2021, 20, 1-10.	1.0	3
14	Comment on “Deterministic Sensitivity Analysis Under Ignorance”. <i>Pharmacoeconomics</i> , 2021, 39, 1199-1199.	1.7	0
15	The Application and Implications of Novel Deterministic Sensitivity Analysis Methods. <i>Pharmacoeconomics</i> , 2021, 39, 1-17.	1.7	21
16	Drug Repurposing for Rare Diseases: A Role for Academia. <i>Frontiers in Pharmacology</i> , 2021, 12, 746987.	1.6	18
17	Missing trials in drug regulatory dossiers may have good reasons, but should be predefined and transparent. <i>Journal of Clinical Epidemiology</i> , 2021, , .	2.4	2
18	Selection of Blood, Blood Components, and Blood Products as Essential Medicines in 105 Low- and Middle-Income Countries. <i>Transfusion Medicine Reviews</i> , 2020, 34, 94-100.	0.9	5

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19	Getting the Right Evidence After Drug Approval. <i>Frontiers in Pharmacology</i> , 2020, 11, 569535.	1.6	10
20	Advanced therapy medicinal product manufacturing under the hospital exemption and other exemption pathways in seven European Union countries. <i>Cytotherapy</i> , 2020, 22, 592-600.	0.3	18
21	Impact of a global leader on pharmaceutical practice and policy around the world. <i>Journal of Pharmaceutical Policy and Practice</i> , 2020, 13, .	1.1	0
22	A Review of Methodological Considerations for Economic Evaluations of Gene Therapies and Their Application in Literature. <i>Value in Health</i> , 2020, 23, 1268-1280.	0.1	14
23	Benchmarking health technology assessment agenciesâ€™ methodological challenges and recommendations. <i>International Journal of Technology Assessment in Health Care</i> , 2020, 36, 332-348.	0.2	3
24	Companiesâ€™ Health Technology Assessment Strategies and Practices in Australia, Canada, England, France, Germany, Italy and Spain: An Industry Metrics Study. <i>Frontiers in Pharmacology</i> , 2020, 11, 594549.	1.6	12
25	Assessment of significant benefit for orphan medicinal products by European regulators may support subsequent relative effectiveness assessments by health technology assessment organizations. <i>Drug Discovery Today</i> , 2020, 25, 1223-1231.	3.2	11
26	Decision Making Under Uncertainty: Comparing Regulatory and Health Technology Assessment Reviews of Medicines in the United States and Europe. <i>Clinical Pharmacology and Therapeutics</i> , 2020, 108, 350-357.	2.3	41
27	Efficacy gap between phase II and subsequent phase III studies in oncology. <i>British Journal of Clinical Pharmacology</i> , 2020, 86, 1306-1313.	1.1	8
28	Development and Regulation of Gene and Cell-Based Therapies in Europe: A Quantification and Reflection. <i>Trends in Pharmacological Sciences</i> , 2020, 41, 67-71.	4.0	5
29	The association between receptor binding affinity and metabolic side effect profile of antipsychotics and major cardio- and cerebrovascular events: A case/non-case study using VigiBase. <i>European Neuropsychopharmacology</i> , 2020, 35, 30-38.	0.3	5
30	Enabling appropriate use of antibiotics: review of European Union procedures of harmonising product information, 2007 to 2020. <i>Eurosurveillance</i> , 2020, 25, .	3.9	4
31	Postauthorization Changes to Specific Obligations of Conditionally Authorized Medicines in the European Union: A Retrospective Cohort Study. <i>Clinical Pharmacology and Therapeutics</i> , 2019, 105, 426-435.	2.3	12
32	Phase I/II Clinical Trial-Based Early Economic Evaluation of Acalabrutinib for Relapsed Chronic Lymphocytic Leukaemia. <i>Applied Health Economics and Health Policy</i> , 2019, 17, 883-893.	1.0	15
33	Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions. <i>Value in Health</i> , 2019, 22, 1275-1282.	0.1	65
34	Added therapeutic value of new drugs approved in Brazil from 2004 to 2016. <i>Cadernos De Saude Publica</i> , 2019, 35, e00070018.	0.4	6
35	Prescribing patterns and compliance with World Health Organization recommendations for the management of severe malaria: a modified cohort event monitoring study in public health facilities in Ghana and Uganda. <i>Malaria Journal</i> , 2019, 18, 36.	0.8	14
36	Health-related quality of life in adults with type 2 diabetes mellitus starting with new glucose lowering drugs: An inception cohort study. <i>Primary Care Diabetes</i> , 2019, 13, 221-232.	0.9	5

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37	Postmarketing dosing changes in the label of biologicals. <i>British Journal of Clinical Pharmacology</i> , 2019, 85, 715-721.	1.1	4
38	Exploring the Association between Monoclonal Antibodies and Depression and Suicidal Ideation and Behavior: A VigiBase Study. <i>Drug Safety</i> , 2019, 42, 887-895.	1.4	23
39	Weighing of Evidence by Health Technology Assessment Bodies: Retrospective Study of Reimbursement Recommendations for Conditionally Approved Drugs. <i>Clinical Pharmacology and Therapeutics</i> , 2019, 105, 684-691.	2.3	34
40	Access to Strong Opioid Analgesics in the Context of Legal and Regulatory Barriers in Eleven Central and Eastern European Countries. <i>Journal of Palliative Medicine</i> , 2018, 21, 963-969.	0.6	8
41	Building Synergy between Regulatory and HTA Agencies beyond Processes and Procedures – Can We Effectively Align the Evidentiary Requirements? A Survey of Stakeholder Perceptions. <i>Value in Health</i> , 2018, 21, 707-714.	0.1	30
42	Global Regulatory Differences for Gene- and Cell-Based Therapies: Consequences and Implications for Patient Access and Therapeutic Innovation. <i>Clinical Pharmacology and Therapeutics</i> , 2018, 103, 120-127.	2.3	22
43	When More Is Less: An Exploratory Study of the Precautionary Reporting Bias and Its Impact on Safety Signal Detection. <i>Clinical Pharmacology and Therapeutics</i> , 2018, 103, 296-303.	2.3	17
44	Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems. <i>Globalization and Health</i> , 2018, 14, 102.	2.4	46
45	Organizational capacities of national pharmacovigilance centres in Africa: assessment of resource elements associated with successful and unsuccessful pharmacovigilance experiences. <i>Globalization and Health</i> , 2018, 14, 109.	2.4	27
46	Challenges in Advanced Therapy Medicinal Product Development: A Survey among Companies in Europe. <i>Molecular Therapy - Methods and Clinical Development</i> , 2018, 11, 121-130.	1.8	63
47	Drug Shortages From the Perspectives of Authorities and Pharmacy Practice in the Netherlands: An Observational Study. <i>Frontiers in Pharmacology</i> , 2018, 9, 1243.	1.6	14
48	Effect of different methods for estimating persistence and adherence to new glucose-lowering drugs: results of an observational, inception cohort study in Portugal. <i>Patient Preference and Adherence</i> , 2018, Volume 12, 1471-1482.	0.8	4
49	The future of drug development: the paradigm shift towards systems therapeutics. <i>Drug Discovery Today</i> , 2018, 23, 1990-1995.	3.2	21
50	Increased risk of all-cause mortality associated with domperidone use in Parkinson's patients: a population-based cohort study in the UK. <i>British Journal of Clinical Pharmacology</i> , 2018, 84, 2551-2561.	1.1	10
51	Factors related to drug approvals: predictors of outcome?. <i>Drug Discovery Today</i> , 2017, 22, 937-946.	3.2	8
52	Primary endpoint discrepancies were found in one in ten clinical drug trials. Results of an inception cohort study. <i>Journal of Clinical Epidemiology</i> , 2017, 89, 199-208.	2.4	10
53	Recruitment failure and futility were the most common reasons for discontinuation of clinical drug trials. Results of a nationwide inception cohort study in the Netherlands. <i>Journal of Clinical Epidemiology</i> , 2017, 88, 140-147.	2.4	12
54	Differences in VigiBase® reporting of aminoglycoside and capreomycin-suspected ototoxicity during tuberculosis treatment. <i>Pharmacoepidemiology and Drug Safety</i> , 2017, 26, 1-8.	0.9	18

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55	FDA Facilitated Regulatory Pathways: Visualizing Their Characteristics, Development, and Authorization Timelines. <i>Frontiers in Pharmacology</i> , 2017, 8, 161.	1.6	21
56	A DECADE OF HEALTH TECHNOLOGY ASSESSMENT IN POLAND. <i>International Journal of Technology Assessment in Health Care</i> , 2017, 33, 350-357.	0.2	10
57	Risk of hypoglycaemia in users of sulphonylureas compared with metformin in relation to renal function and sulphonylurea metabolite group: population based cohort study. <i>BMJ</i> , The, 2016, 354, i3625.	3.0	65
58	The effect of exposure misclassification in spontaneous ADR reports on the time to detection of product-specific risks for biologicals: a simulation study. <i>Pharmacoepidemiology and Drug Safety</i> , 2016, 25, 297-306.	0.9	8
59	Characteristics and follow-up of postmarketing studies of conditionally authorized medicines in the EU. <i>British Journal of Clinical Pharmacology</i> , 2016, 82, 213-226.	1.1	42
60	Predicting the 10-year risk of hip and major osteoporotic fracture in rheumatoid arthritis and in the general population: an independent validation and update of UK FRAX without bone mineral density. <i>Annals of the Rheumatic Diseases</i> , 2016, 75, 2095-2100.	0.5	32
61	Licensing failure in the European decentralised procedure. <i>European Journal of Pharmaceutical Sciences</i> , 2016, 87, 47-51.	1.9	0
62	Understanding inconsistency in the results from observational pharmacoepidemiological studies: the case of antidepressant use and risk of hip/femur fractures. <i>Pharmacoepidemiology and Drug Safety</i> , 2016, 25, 88-102.	0.9	23
63	Validity of diagnostic codes and laboratory measurements to identify patients with idiopathic acute liver injury in a hospital database. <i>Pharmacoepidemiology and Drug Safety</i> , 2016, 25, 21-28.	0.9	14
64	Extensions of indication throughout the drug product lifecycle: a quantitative analysis. <i>Drug Discovery Today</i> , 2016, 21, 348-355.	3.2	21
65	Non-Publication Is Common among Phase 1, Single-Center, Not Prospectively Registered, or Early Terminated Clinical Drug Trials. <i>PLoS ONE</i> , 2016, 11, e0167709.	1.1	20
66	Outcomes of a Postexposure Prophylaxis Program at the Korle-Bu Teaching Hospital in Ghana. <i>Journal of the International Association of Providers of AIDS Care</i> , 2015, 14, 544-552.	0.6	5
67	Remission of Type 2 Diabetes Mellitus in Patients After Different Types of Bariatric Surgery. <i>JAMA Surgery</i> , 2015, 150, 1126.	2.2	90
68	Observations on Three Endpoint Properties and Their Relationship to Regulatory Outcomes of European Oncology Marketing Applications. <i>Oncologist</i> , 2015, 20, 683-691.	1.9	7
69	Patterns of glucose lowering drugs utilization in Portugal and in the Netherlands. Trends over time. <i>Primary Care Diabetes</i> , 2015, 9, 482-489.	0.9	17
70	Adverse events and adherence to HIV post-exposure prophylaxis: a cohort study at the Korle-Bu Teaching Hospital in Accra, Ghana. <i>BMC Public Health</i> , 2015, 15, 573.	1.2	12
71	The Epidemiology of Hip and Major Osteoporotic Fractures in a Dutch Population of Community-Dwelling Elderly: Implications for the Dutch FRAX® Algorithm. <i>PLoS ONE</i> , 2015, 10, e0143800.	1.1	20
72	Essential Medicines Are More Available than Other Medicines around the Globe. <i>PLoS ONE</i> , 2014, 9, e87576.	1.1	85

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73	Selection of Essential Medicines for Diabetes in Low and Middle Income Countries: A Survey of 32 National Essential Medicines Lists. PLoS ONE, 2014, 9, e106072.	1.1	24
74	Essential medicines for COPD and asthma in low and middle-income countries. Thorax, 2014, 69, 1149-1151.	2.7	35
75	The Use of Surrogate Endpoints in Regulating Medicines for Cardio-Renal Disease: Opinions of Stakeholders. PLoS ONE, 2014, 9, e108722.	1.1	11
76	Statins, systemic inflammation and risk of death in COPD: The Rotterdam study. Pulmonary Pharmacology and Therapeutics, 2013, 26, 212-217.	1.1	102
77	Drug development for exceptionally rare metabolic diseases: challenging but not impossible. Orphanet Journal of Rare Diseases, 2013, 8, 179.	1.2	14
78	Factors influencing non-approval of new drugs in Europe. Nature Reviews Drug Discovery, 2012, 11, 903-904.	21.5	26
79	Determinants for successful marketing authorisation of orphan medicinal products in the EU. Drug Discovery Today, 2012, 17, 352-358.	3.2	23
80	Characteristics of orphan drug applications that fail to achieve marketing approval in the USA. Drug Discovery Today, 2011, 16, 73-80.	3.2	37
81	Superior efficacy of new medicines?. European Journal of Clinical Pharmacology, 2010, 66, 445-448.	0.8	33
82	Measuring exacerbations in obstructive lung disease. Pharmacoepidemiology and Drug Safety, 2010, 19, 367-374.	0.9	6
83	Effects of glucocorticoids on the neutrophil count: A cohort study among hospitalized patients. Pulmonary Pharmacology and Therapeutics, 2010, 23, 129-134.	1.1	11
84	Hematocytometry analysis as discriminative marker for asthma phenotypes. Clinical Chemistry and Laboratory Medicine, 2009, 47, 573-8.	1.4	7
85	Translation of rare disease research into orphan drug development: disease matters. Drug Discovery Today, 2009, 14, 1166-1173.	3.2	67
86	Evaluation of Post-Authorization Safety Studies in the First Cohort of EU Risk Management Plans at Time of Regulatory Approval. Drug Safety, 2009, 32, 1175-1187.	1.4	46
87	Identification of exacerbations in obstructive lung disease through biomarkers. Biomarkers, 2009, 14, 523-528.	0.9	11
88	Predictors of orphan drug approval in the European Union. European Journal of Clinical Pharmacology, 2008, 64, 545-552.	0.8	42
89	Gap in publication of comparative information on new medicines. British Journal of Clinical Pharmacology, 2008, 65, 716-722.	1.1	7
90	Orphan drug development across Europe: bottlenecks and opportunities. Drug Discovery Today, 2008, 13, 670-676.	3.2	24

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91	Choice of Comparator in Active Control Trials of New Drugs. <i>Annals of Pharmacotherapy</i> , 2008, 42, 1605-1615.	0.9	14
92	Use of beta-2 agonists and risk of hip/femur fracture: a population-based case-control study. <i>Pharmacoepidemiology and Drug Safety</i> , 2007, 16, 612-619.	0.9	58
93	Availability of comparative trials for the assessment of new medicines in the European Union at the moment of market authorization. <i>British Journal of Clinical Pharmacology</i> , 2007, 63, 159-162.	1.1	46
94	Rare essentials drugs for rare diseases as essential medicines. <i>Bulletin of the World Health Organization</i> , 2006, 84, 745-751.	1.5	87
95	Challenges and Opportunities for Companies to Build HTA/Payer Perspectives Into Drug Development Through the Use of a Dynamic Target Product Profile. <i>Frontiers in Pharmacology</i> , 0, 13, .	1.6	1