Hubert G M Leufkens

List of Publications by Year
in descending order

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95 papers	2,005 citations	279798 23 h-index	315739 38 g-index
95 all docs	95 docs citations	95 times ranked	2638 citing authors

#	Article	IF	Citations
1	Building HTA insights into the drug development plan: Current approaches to seeking early scientific advice from HTA agencies. Drug Discovery Today, 2022, 27, 347-353.	6.4	6
2	Unmet Medical Need as a Driver for Pharmaceutical Sciences â€“ A Survey Among Scientists. Journal of Pharmaceutical Sciences, 2022, 111, 1318-1324.	3.3	6
3	Preâ€approval and postâ€approval availability of evidence and clinical benefit of conditionally approved cancer drugs in Europe: A comparison with standard approved cancer drugs. British Journal of Clinical Pharmacology, 2022, 88, 2169-2179.	2.4	5
4	Addressing uncertainty in relative effectiveness assessments by HTA organizations. International Journal of Technology Assessment in Health Care, 2022, 38, e17.	0.5	3
5	Key Considerations in the Health Technology Assessment of Advanced Therapy Medicinal Products in Scotland, The Netherlands, and England. Value in Health, 2022, 25, 390-399.	0.3	8
6	Market access to new anticancer medicines for children and adolescents with cancer in Europe. European Journal of Cancer, 2022, 165, 146-153.	2.8	9
7	The impact of FDA and EMA regulatory decision-making process on the access to CFTR modulators for the treatment of cystic fibrosis. Orphanet Journal of Rare Diseases, 2022, 17, 188.	2.7	24
8	Regulatory Safety Learning Driven by the Mechanism of Action: The Case of TNFâ€Î± Inhibitors. Clinical Pharmacology and Therapeutics, 2021, 110, 123-131.	4.7	4
9	Estimation of manufacturing development costs of cell-based therapies: a feasibility study. Cytotherapy, 2021, 23, 730-739.	0.7	12
10	Regulatory density as a means to refine current regulatory approaches for increasingly complex medicines. Drug Discovery Today, 2021, 26, 2221-2225.	6.4	2
11	Associations between uncertainties identified by the European Medicines Agency and national decision making on reimbursement by HTA agencies. Clinical and Translational Science, 2021, 14, 1566-1577.	3.1	10
12	Early Cost-Effectiveness of Onasemnogene Abeparvovec-xioi (Zolgensma) and Nusinersen (Spinraza) Treatment for Spinal Muscular Atrophy I in The Netherlands With Relapse Scenarios. Value in Health, 2021, 24, 759-769.	0.3	24
13	Comprehensive evaluation of post-approval regulatory actions during the drug lifecycle â€“ a focus on benefits and risks. Expert Opinion on Drug Safety, 2021, 20, 1-10.	2.4	3
14	Comment on â€œDeterministic Sensitivity Analysis Under Ignoranceâ€. Pharmacoeconomics, 2021, 39, 1199-1199.	3.3	0
15	The Application and Implications of Novel Deterministic Sensitivity Analysis Methods. Pharmacoeconomics, 2021, 39, 1-17.	3.3	21
16	Drug Repurposing for Rare Diseases: A Role for Academia. Frontiers in Pharmacology, 2021, 12, 746987.	3.5	18
17	Missing trials in drug regulatory dossiers may have good reasons, but should be predefined and transparent. Journal of Clinical Epidemiology, 2021, , .	5.0	2
18	Selection of Blood, Blood Components, and Blood Products as Essential Medicines in 105 Low- and Middle-Income Countries. Transfusion Medicine Reviews, 2020, 34, 94-100.	2.0	5

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19	Getting the Right Evidence After Drug Approval. Frontiers in Pharmacology, 2020, 11, 569535.	3.5	10
20	Advanced therapy medicinal product manufacturing under the hospital exemption and other exemption pathways in seven European Union countries. Cytotherapy, 2020, 22, 592-600.	0.7	18
21	Impact of a global leader on pharmaceutical practice and policy around the world. Journal of Pharmaceutical Policy and Practice, 2020, 13, .	2.4	0
22	A Review of Methodological Considerations for Economic Evaluations of Gene Therapies and Their Application in Literature. Value in Health, 2020, 23, 1268-1280.	0.3	14
23	Benchmarking health technology assessment agenciesâ€"methodological challenges and recommendations. International Journal of Technology Assessment in Health Care, 2020, 36, 332-348.	0.5	3
24	Companiesâ€™ Health Technology Assessment Strategies and Practices in Australia, Canada, England, France, Germany, Italy and Spain: An Industry Metrics Study. Frontiers in Pharmacology, 2020, 11, 594549.	3.5	12
25	Assessment of significant benefit for orphan medicinal products by European regulators may support subsequent relative effectiveness assessments by health technology assessment organizations. Drug Discovery Today, 2020, 25, 1223-1231.	6.4	11
26	Decision Making Under Uncertainty: Comparing Regulatory and Health Technology Assessment Reviews of Medicines in the United States and Europe. Clinical Pharmacology and Therapeutics, 2020, 108, 350-357.	4.7	41
27	Efficacy gap between phase II and subsequent phase III studies in oncology. British Journal of Clinical Pharmacology, 2020, 86, 1306-1313.	2.4	8
28	Development and Regulation of Gene and Cell-Based Therapies in Europe: A Quantification and Reflection. Trends in Pharmacological Sciences, 2020, 41, 67-71.	8.7	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. European Neuropsychopharmacology, 2020, 35, 30-38.	0.7	5
30	Enabling appropriate use of antibiotics: review of European Union procedures of harmonising product information, 2007 to 2020. Eurosurveillance, 2020, 25, .	7.0	4
31	Postauthorization Changes to Specific Obligations of Conditionally Authorized Medicines in the European Union: AÂRetrospective Cohort Study. Clinical Pharmacology and Therapeutics, 2019, 105, 426-435.	4.7	12
32	Phase I/II Clinical Trial-Based Early Economic Evaluation of Acalabrutinib for Relapsed Chronic Lymphocytic Leukaemia. Applied Health Economics and Health Policy, 2019, 17, 883-893.	2.1	15
33	Unmet Medical Need: An Introduction to Definitions and Stakeholder Perceptions. Value in Health, 2019, 22, 1275-1282.	0.3	65
34	Added therapeutic value of new drugs approved in Brazil from 2004 to 2016. Cadernos De Saude Publica, 2019, 35, e00070018.	1.0	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. Malaria Journal, 2019, 18, 36.	2.3	14
36	Health-related quality of life in adults with type 2 diabetes mellitus starting with new glucose lowering drugs: An inception cohort study. Primary Care Diabetes, 2019, 13, 221-232.	1.8	5

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37	Postâ€marketing dosing changes in the label of biologicals. British Journal of Clinical Pharmacology, 2019, 85, 715-721.	2.4	4
38	Exploring the Association between Monoclonal Antibodies and Depression and Suicidal Ideation and Behavior: A VigiBase Study. Drug Safety, 2019, 42, 887-895.	3.2	23
39	Weighing of Evidence by Health Technology Assessment Bodies: Retrospective Study of Reimbursement Recommendations for Conditionally Approved Drugs. Clinical Pharmacology and Therapeutics, 2019, 105, 684-691.	4.7	34
40	Access to Strong Opioid Analgesics in the Context of Legal and Regulatory Barriers in Eleven Central and Eastern European Countries. Journal of Palliative Medicine, 2018, 21, 963-969.	1.1	8
41	Building Synergy between Regulatory and HTA Agencies beyond Processes and Proceduresâ€”Can We Effectively Align the Evidentiary Requirements? A Survey of Stakeholder Perceptions. Value in Health, 2018, 21, 707-714.	0.3	30
42	Global Regulatory Differences for Geneâ€•and Cellâ€Based Therapies: Consequences and Implications for Patient Access and Therapeutic Innovation. Clinical Pharmacology and Therapeutics, 2018, 103, 120-127.	4.7	22
43	When More Is Less: An Exploratory Study of the Precautionary Reporting Bias and Its Impact on Safety Signal Detection. Clinical Pharmacology and Therapeutics, 2018, 103, 296-303.	4.7	17
44	Expanding global access to essential medicines: investment priorities for sustainably strengthening medical product regulatory systems. Globalization and Health, 2018, 14, 102.	4.9	46
45	Organizational capacities of national pharmacovigilance centres in Africa: assessment of resource elements associated with successful and unsuccessful pharmacovigilance experiences. Globalization and Health, 2018, 14, 109.	4.9	27
46	Challenges in Advanced Therapy Medicinal Product Development: A Survey among Companies in Europe. Molecular Therapy - Methods and Clinical Development, 2018, 11, 121-130.	4.1	63
47	Drug Shortages From the Perspectives of Authorities and Pharmacy Practice in the Netherlands: An Observational Study. Frontiers in Pharmacology, 2018, 9, 1243.	3.5	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. Patient Preference and Adherence, 2018, Volume 12, 1471-1482.	1.8	4
49	The future of drug development: the paradigm shift towards systems therapeutics. Drug Discovery Today, 2018, 23, 1990-1995.	6.4	21
50	Increased risk of allâ€cause mortality associated with domperidone use in Parkinson's patients: a populationâ€based cohort study in the UK. British Journal of Clinical Pharmacology, 2018, 84, 2551-2561.	2.4	10
51	Factors related to drug approvals: predictors of outcome?. Drug Discovery Today, 2017, 22, 937-946.	6.4	8
52	Primary endpoint discrepancies were found in one in ten clinical drug trials. Results of an inception cohort study. Journal of Clinical Epidemiology, 2017, 89, 199-208.	5.0	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. Journal of Clinical Epidemiology, 2017, 88, 140-147.	5.0	12
54	Differences in VigiBaseÂ® reporting of aminoglycoside and capreomycinâ€suspected ototoxicity during tuberculosis treatment. Pharmacoepidemiology and Drug Safety, 2017, 26, 1-8.	1.9	18

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55	FDA Facilitated Regulatory Pathways: Visualizing Their Characteristics, Development, and Authorization Timelines. Frontiers in Pharmacology, 2017, 8, 161.	3.5	21
56	A DECADE OF HEALTH TECHNOLOGY ASSESSMENT IN POLAND. International Journal of Technology Assessment in Health Care, 2017, 33, 350-357.	0.5	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. BMJ, The, 2016, 354, i3625.	6.0	65
58	The effect of exposure misclassification in spontaneous ADR reports on the time to detection of productâ€specific risks for biologicals: a simulation study. Pharmacoepidemiology and Drug Safety, 2016, 25, 297-306.	1.9	8
59	Characteristics and followâ€up of postmarketing studies of conditionally authorized medicines in the EU. British Journal of Clinical Pharmacology, 2016, 82, 213-226.	2.4	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. Annals of the Rheumatic Diseases, 2016, 75, 2095-2100.	0.9	32
61	Licensing failure in the European decentralised procedure. European Journal of Pharmaceutical Sciences, 2016, 87, 47-51.	4.0	0
62	Understanding inconsistency in the results from observational pharmacoepidemiological studies: the case of antidepressant use and risk of hip/femur fractures. Pharmacoepidemiology and Drug Safety, 2016, 25, 88-102.	1.9	23
63	Validity of diagnostic codes and laboratory measurements to identify patients with idiopathic acute liver injury in a hospital database. Pharmacoepidemiology and Drug Safety, 2016, 25, 21-28.	1.9	14
64	Extensions of indication throughout the drug product lifecycle: a quantitative analysis. Drug Discovery Today, 2016, 21, 348-355.	6.4	21
65	Non-Publication Is Common among Phase 1, Single-Center, Not Prospectively Registered, or Early Terminated Clinical Drug Trials. PLoS ONE, 2016, 11, e0167709.	2.5	20
66	Outcomes of a Postexposure Prophylaxis Program at the Korle-Bu Teaching Hospital in Ghana. Journal of the International Association of Providers of AIDS Care, 2015, 14, 544-552.	1.5	5
67	Remission of Type 2 Diabetes Mellitus in Patients After Different Types of Bariatric Surgery. JAMA Surgery, 2015, 150, 1126.	4.3	90
68	Observations on Three Endpoint Properties and Their Relationship to Regulatory Outcomes of European Oncology Marketing Applications. Oncologist, 2015, 20, 683-691.	3.7	7
69	Patterns of glucose lowering drugs utilization in Portugal and in the Netherlands. Trends over time. Primary Care Diabetes, 2015, 9, 482-489.	1.8	17
70	Adverse events and adherence to HIV post-exposure prophylaxis: a cohort study at the Korle-Bu Teaching Hospital in Accra, Ghana. BMC Public Health, 2015, 15, 573.	2.9	12
71	The Epidemiology of Hip and Major Osteoporotic Fractures in a Dutch Population of Community-Dwelling Elderly: Implications for the Dutch FRAXÂ® Algorithm. PLoS ONE, 2015, 10, e0143800.	2.5	20
72	Essential Medicines Are More Available than Other Medicines around the Globe. PLoS ONE, 2014, 9, e87576.	2.5	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.	2.5	24
74	Essential medicines for COPD and asthma in low and middle-income countries. Thorax, 2014, 69, 1149-1151.	5.6	35
75	The Use of Surrogate Endpoints in Regulating Medicines for Cardio-Renal Disease: Opinions of Stakeholders. PLoS ONE, 2014, 9, e108722.	2.5	11
76	Statins, systemic inflammation and risk of death in COPD: The Rotterdam study. Pulmonary Pharmacology and Therapeutics, 2013, 26, 212-217.	2.6	102
77	Drug development for exceptionally rare metabolic diseases: challenging but not impossible. Orphanet Journal of Rare Diseases, 2013, 8, 179.	2.7	14
78	Factors influencing non-approval of new drugs in Europe. Nature Reviews Drug Discovery, 2012, 11, 903-904.	46.4	26
79	Determinants for successful marketing authorisation of orphan medicinal products in the EU. Drug Discovery Today, 2012, 17, 352-358.	6.4	23
80	Characteristics of orphan drug applications that fail to achieve marketing approval in the USA. Drug Discovery Today, 2011, 16, 73-80.	6.4	37
81	Superior efficacy of new medicines?. European Journal of Clinical Pharmacology, 2010, 66, 445-448.	1.9	33
82	Measuring exacerbations in obstructive lung disease. Pharmacoepidemiology and Drug Safety, 2010, 19, 367-374.	1.9	6
83	Effects of glucocorticoids on the neutrophil count: A cohort study among hospitalized patients. Pulmonary Pharmacology and Therapeutics, 2010, 23, 129-134.	2.6	11
84	Hematocytometry analysis as discriminative marker for asthma phenotypes. Clinical Chemistry and Laboratory Medicine, 2009, 47, 573-8.	2.3	7
85	Translation of rare disease research into orphan drug development: disease matters. Drug Discovery Today, 2009, 14, 1166-1173.	6.4	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.	3.2	46
87	Identification of exacerbations in obstructive lung disease through biomarkers. Biomarkers, 2009, 14, 523-528.	1.9	11
88	Predictors of orphan drug approval in the European Union. European Journal of Clinical Pharmacology, 2008, 64, 545-552.	1.9	42
89	Gap in publication of comparative information on new medicines. British Journal of Clinical Pharmacology, 2008, 65, 716-722.	2.4	7
90	Orphan drug development across Europe: bottlenecks and opportunities. Drug Discovery Today, 2008, 13, 670-676.	6.4	24

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91	Choice of Comparator in Active Control Trials of New Drugs. Annals of Pharmacotherapy, 2008, 42, 1605-1615.	1.9	14
92	Use of beta-2 agonists and risk of hip/femur fracture: a population-based case-control study. Pharmacoepidemiology and Drug Safety, 2007, 16, 612-619.	1.9	58
93	Availability of comparative trials for the assessment of new medicines in the European Union at the moment of market authorization. British Journal of Clinical Pharmacology, 2007, 63, 159-162.	2.4	46
94	Rare essentials drugs for rare diseases as essential medicines. Bulletin of the World Health Organization, 2006, 84, 745-751.	3.3	87
95	Challenges and Opportunities for Companies to Build HTA/Payer Perspectives Into Drug Development Through the Use of a Dynamic Target Product Profile. Frontiers in Pharmacology, 0, 13, .	3.5	1