Gilbert J Burckart

List of Publications by Year
in descending order

79 papers	3,359 citations	236612 25 h-index	143772 57 g-index
80 all docs	80 docs citations	80 times ranked	2800 citing authors

#	Article	IF	Citations
1	Pediatric Drug Development Studies for Familial Hypercholesterolemia Submitted to the US Food and Drug Administration Between 2007 and 2020. Journal of Clinical Pharmacology, 2022, 62, 397-408.	1.0	2
2	Pediatric clinical pharmacology and therapeutics. , 2022, , 455-477.		0
3	Roadmap to 2030 for Drug Evaluation in Older Adults. Clinical Pharmacology and Therapeutics, 2022, 112, 210-223.	2.3	19
4	Pediatric and Adult Placebo Response Rates in Placeboâ€Controlled Clinical Trials Submitted to the US FDA 2012â€“2020. Journal of Clinical Pharmacology, 2022, , .	1.0	2
5	Ethical Considerations for Pediatric Placebo-Controlled Trials: FDA Outcomes and Perspectives. Therapeutic Innovation and Regulatory Science, 2021, 55, 282-303.	0.8	6
6	Physiologically Based Pharmacokinetic Modeling Framework to Predict Neonatal Pharmacokinetics of Transplacentally Acquired Emtricitabine, Dolutegravir, and Raltegravir. Clinical Pharmacokinetics, 2021, 60, 795-809.	1.6	14
7	Drug Safety in Labeling for Pediatric Drug Development and Dose Selection in Submissions to the US Food and Drug Administration. Journal of Clinical Pharmacology, 2021, 61, S133-S140.	1.0	3
8	Methods Used for Pediatric Dose Selection in Drug Development Programs Submitted to the US FDA 2012â€2020. Journal of Clinical Pharmacology, 2021, 61, S28-S35.	1.0	6
9	Applying the Noninferiority Paradigm to Assess Exposureâ€Response Similarity and Dose Between Pediatric and Adult Patients. Journal of Clinical Pharmacology, 2021, 61, S165-S174.	1.0	3
10	Neonatal and Pediatric Dose Selection: Quo Vadis?. Journal of Clinical Pharmacology, 2021, 61, S7-S8.	1.0	2
11	Progress in Drug Developmentâ€“Pediatric Dose Selection: Workshop Summary. Journal of Clinical Pharmacology, 2021, 61, S13-S21.	1.0	3
12	Evaluation of Physiologically Based Pharmacokinetic Models to Predict the Absorption of BCS Class I Drugs in Different Pediatric Age Groups. Journal of Clinical Pharmacology, 2021, 61, S94-S107.	1.0	1
13	Inclusion of Infants and Neonates in Pediatric Orphan Product Approvals. Clinical Pharmacology and Therapeutics, 2021, 110, 997-1003.	2.3	3
14	Regulatory Considerations for the Mother, Fetus and Neonate in Fetal Pharmacology Modeling. Frontiers in Pediatrics, 2021, 9, 698611.	0.9	8
15	Mechanistic Modeling of Placental Drug Transfer in Humans: How Do Differences in Maternal/Fetal Fraction of Unbound Drug and Placental Influx/Efflux Transfer Rates Affect Fetal Pharmacokinetics?. Frontiers in Pediatrics, 2021, 9, 723006.	0.9	7
16	International Coherence of Pediatric Drug Labeling for Drug Safety: Comparison of Approved Labels in Korea and the United States. Clinical Pharmacology and Therapeutics, 2020, 107, 530-540.	2.3	6
17	Physiologically Based Pharmacokinetic Models to Predict Maternal Pharmacokinetics and Fetal Exposure to Emtricitabine and Acyclovir. Journal of Clinical Pharmacology, 2020, 60, 240-255.	1.0	34
18	The RACE to Develop New Targeted Therapies for Children With CNS Tumors. Clinical Pharmacology and Therapeutics, 2020, 108, 434-436.	2.3	3

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19	Approaches to Dose Finding in Neonates, Illustrating the Variability between Neonatal Drug Development Programs. Pharmaceutics, 2020, 12, 685.	2.0	20
20	Combined Pediatric and Adult Trials Submitted to the US Food and Drug Administration 2012â€“2018. Clinical Pharmacology and Therapeutics, 2020, 108, 1018-1025.	2.3	15
21	Prediction of Maternal and Fetal Pharmacokinetics of Dolutegravir and Raltegravir Using Physiologically Based Pharmacokinetic Modeling. Clinical Pharmacokinetics, 2020, 59, 1433-1450.	1.6	16
22	Dosing Recommendations for Pediatric Patients With Renal Impairment. Journal of Clinical Pharmacology, 2020, 60, 1551-1560.	1.0	6
23	Exposureâ€“Response Assessment in Pediatric Drug Development Studies Submitted to the US Food and Drug Administration. Clinical Pharmacology and Therapeutics, 2020, 108, 90-98.	2.3	14
24	Scientific and Regulatory Considerations for an Ontogeny Knowledge Base for Pediatric Clinical Pharmacology. Clinical Pharmacology and Therapeutics, 2020, 107, 707-709.	2.3	3
25	Extrapolation of Adult Efficacy to Pediatric Patients With Chemotherapyâ€Induced Nausea and Vomiting. Journal of Clinical Pharmacology, 2020, 60, 775-784.	1.0	3
26	The Revolution in Pediatric Drug Development and Drug Use: Therapeutic Orphans No More. Journal of Pediatric Pharmacology and Therapeutics, 2020, 25, 565-573.	0.3	19
27	Surrogate Endpoints in Pediatric Studies Submitted to the US FDA. Clinical Pharmacology and Therapeutics, 2019, 105, 555-557.	2.3	5
28	Pediatric Renal Ontogeny and Applications in Drug Development. Journal of Clinical Pharmacology, 2019, 59, S9-S20.	1.0	11
29	Pediatric Ontogeny: Moving From Translational Science to Drug Development. Journal of Clinical Pharmacology, 2019, 59, S7-S8.	1.0	4
30	Incorporating Ontogeny in Physiologically Based Pharmacokinetic Modeling to Improve Pediatric Drug Development: What We Know About Developmental Changes in Membrane Transporters. Journal of Clinical Pharmacology, 2019, 59, S56-S69.	1.0	23
31	Predicting the pharmacokinetics of piperacillin and tazobactam in preterm and term neonates using physiologically based pharmacokinetic modeling. Computational Toxicology, 2019, 12, 100104.	1.8	4
32	A Comparison of Pediatric and Adult Safety Studies for Antipsychotic and Antidepressant Drugs Submitted to the United States Food and Drug Administration. Journal of Pediatrics, 2019, 208, 236-242.e3.	0.9	32
33	Ontogeny equations with probability distributions for anthropomorphic measurements in preterm and term neonates and infants for use in a PBPK model. Computational Toxicology, 2019, 11, 101-117.	1.8	9
34	Monoclonal Antibodies and Fcâ€Fusion Proteins for Pediatric Use: Dosing, Immunogenicity, and Modeling and Simulation in Data Submitted to the US Food and Drug Administration. Journal of Clinical Pharmacology, 2019, 59, 1130-1143.	1.0	25
35	Renal Clearance in Newborns and Infants: Predictive Performance of Populationâ€Based Modeling for Drug Development. Clinical Pharmacology and Therapeutics, 2019, 105, 1462-1470.	2.3	27
36	Dosage Considerations for Canakinumab in Children With Periodic Fever Syndromes. Clinical Pharmacology and Therapeutics, 2019, 106, 557-567.	2.3	14

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37	Pediatric Drugâ€“Drug Interaction Studies: Barriers and Opportunities. Clinical Pharmacology and Therapeutics, 2019, 105, 1067-1070.	2.3	27
38	Primary Endpoints in Pediatric Efficacy Trials Submitted to the US FDA. Journal of Clinical Pharmacology, 2018, 58, 885-890.	1.0	19
39	Pediatric Drug Development: Outlook for Scienceâ€Based Innovation. Clinical Pharmacology and Therapeutics, 2018, 103, 376-378.	2.3	27
40	Obesity and Pediatric Drug Development. Journal of Clinical Pharmacology, 2018, 58, 650-661.	1.0	20
41	Pediatric Development of Molecularly Targeted Oncology Drugs. Clinical Pharmacology and Therapeutics, 2018, 104, 384-389.	2.3	5
42	Enrichment Strategies in Pediatric Drug Development: An Analysis of Trials Submitted to the US Food and Drug Administration. Clinical Pharmacology and Therapeutics, 2018, 104, 983-988.	2.3	7
43	Neonatal Safety Information Reported to the FDA During Drug Development Studies. Therapeutic Innovation and Regulatory Science, 2018, 52, 100-108.	0.8	27
44	Glomerular Filtration Rate Estimation Formulas for Pediatric and Neonatal Use. Journal of Pediatric Pharmacology and Therapeutics, 2018, 23, 424-431.	0.3	36
45	Bridging Adult Experience to Pediatrics in Oncology Drug Development. Journal of Clinical Pharmacology, 2017, 57, S129-S135.	1.0	5
46	Physiologically Based Pharmacokinetic Prediction of Linezolid and Emtricitabine in Neonates and Infants. Clinical Pharmacokinetics, 2017, 56, 383-394.	1.6	16
47	Bone Mineral Density to Assess Pediatric Bone Health in Drug Development. Therapeutic Innovation and Regulatory Science, 2017, 51, 756-760.	0.8	2
48	Exposure Matching for Extrapolation of Efficacy in Pediatric Drug Development. Journal of Clinical Pharmacology, 2016, 56, 1326-1334.	1.0	58
49	Pediatric Drug Development and the Regulatory Changes That Are Creating the Science of Pediatric Dosing. , 2016, , 1-12.		0
50	Predicting neonatal pharmacokinetics from prior data using population pharmacokinetic modeling. Journal of Clinical Pharmacology, 2015, 55, 1175-1183.	1.0	16
51	Adverse Event Detection and Labeling in Pediatric Drug Development: Antiretroviral Drugs. Therapeutic Innovation and Regulatory Science, 2015, 49, 302-309.	0.8	10
52	Drug development for pediatric neurogenic bladder dysfunction: Dosing, endpoints, and study design. Journal of Clinical Pharmacology, 2014, 54, 1239-1246.	1.0	5
53	Adolescent Dosing and Labeling Since the Food and Drug Administration Amendments Act of 2007. JAMA Pediatrics, 2013, 167, 926.	3.3	89
54	Methodological Issues in the Design of Paediatric Pharmacokinetic Studies. Pharmaceutical Medicine, 2012, 26, 13-22.	1.0	3

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55	Identification of Factors Affecting Tacrolimus Level and 5â€Year Clinical Outcome in Kidney Transplant Patients. Basic and Clinical Pharmacology and Toxicology, 2012, 111, 217-223.	1.2	23
56	Translational Biomarkers: from Preclinical to Clinical a Report of 2009 AAPS/ACCP Biomarker Workshop. AAPS Journal, 2011, 13, 274-283.	2.2	29
57	Extrapolation of Adult Data and Other Data in Pediatric Drug-Development Programs. Pediatrics, 2011, 128, e1242-e1249.	1.0	259
58	Understanding the Genetic Basis for Adverse Drug Effects: The Calcineurin Inhibitors. Pharmacotherapy, 2010, 30, 195-209.	1.2	22
59	Update on the clinical pharmacogenomics of organ transplantation. Pharmacogenomics, 2010, 11, 227-236.	0.6	19
60	Pharmacogenomic Biomarker Information in Drug Labels Approved by the United States Food and Drug Administration: Prevalence of Related Drug Use. Pharmacotherapy, 2008, 28, 992-998.	1.2	272
61	Qualification of Biomarkers for Drug Development in Organ Transplantation. American Journal of Transplantation, 2008, 8, 267-270.	2.6	30
62	The impact of P-glycoprotein and Mrp2 on mycophenolic acid levels in mice. Transplant Immunology, 2008, 19, 192-196.	0.6	38
63	Pharmacogenomics: The Key to Improved Drug Therapy in Transplant Patients. Clinics in Laboratory Medicine, 2008, 28, 411-422.	0.7	11
64	Genetic Polymorphisms Impact the Risk of Acute Rejection in Pediatric Heart Transplantation: A Multi-Institutional Study. Transplantation, 2008, 85, 1632-1639.	0.5	56
65	A novel variant L263F in human inosine 5â€²-monophosphate dehydrogenase 2 is associated with diminished enzyme activity. Pharmacogenetics and Genomics, 2007, 17, 283-290.	0.7	47
66	Looking beneath the surface of the CYP3A5 polymorphism. Pediatric Transplantation, 2007, 11, 239-240.	0.5	3
67	Progress in the Direct Application of Pharmacogenomics to Patient Care: Sustaining innovation. Biomolecules and Therapeutics, 2007, 15, 1-6.	1.1	3
68	Impact of ABCB1 (MDR1) haplotypes on tacrolimus dosing in adult lung transplant patients who are CYP3A5 *3/*3 nonexpressors. Transplant Immunology, 2006, 15, 235-240.	0.6	63
69	Pharmacogenetics in Transplant Patients. Therapeutic Drug Monitoring, 2006, 28, 23-30.	1.0	34
70	Disparate Distribution of 16 Candidate Single Nucleotide Polymorphisms Among Racial and Ethnic Groups of Pediatric Heart Transplant Patients. Transplantation, 2006, 82, 1774-1780.	0.5	67
71	Ciclosporin aerosol in lung transplantation. Expert Opinion on Investigational Drugs, 2006, 15, 981-986.	1.9	2
72	Tacrolimus Dosing in Adult Lung Transplant Patients Is Related to Cytochrome P4503A5 Gene Polymorphism. Journal of Clinical Pharmacology, 2004, 44, 135-140.	1.0	130

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73	Tacrolimus Dosing in Pediatric Heart Transplant Patients is Related to CYP3A5 and MDR1 Gene Polymorphisms. American Journal of Transplantation, 2003, 3, 477-483.	2.6	239
74	The MDR1 polymorphisms at exons 21 and 26 predict steroid weaning in pediatric heart transplant patients. Human Immunology, 2002, 63, 765-770.	1.2	98
75	Clinical Pharmacokinetics of Tacrolimus. Clinical Pharmacokinetics, 1995, 29, 404-430.	1.6	671
76	Clinical Pharmacokinetics in Organ Transplant Patients. Clinical Pharmacokinetics, 1989, 16, 134-161.	1.6	57
77	Clinical Pharmacokinetics of Cyclosporin. Clinical Pharmacokinetics, 1986, 11, 107-132.	1.6	431
78	Rectal thiopental versus an intramuscular cocktail for sedating children before computerized tomography. American Journal of Health-System Pharmacy, 1980, 37, 222-224.	0.5	11
79	Applications of Pharmacogenomics to Pediatric Drug Development. , 0, , 316-331.		0