

# Gilbert J Burckart

## List of Publications by Year in descending order

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Version: 2024-02-01

79  
papers

3,359  
citations

236925

25  
h-index

144013

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. <i>Journal of Clinical Pharmacology</i> , 2022, 62, 397-408.	2.0	2
2	<i>Pediatric clinical pharmacology and therapeutics.</i> , 2022, , 455-477.		0
3	Roadmap to 2030 for Drug Evaluation in Older Adults. <i>Clinical Pharmacology and Therapeutics</i> , 2022, 112, 210-223.	4.7	19
4	Pediatric and Adult Placebo Response Rates in Placeboâ€Controlled Clinical Trials Submitted to the US FDA 2012â€2020. <i>Journal of Clinical Pharmacology</i> , 2022, , .	2.0	2
5	Ethical Considerations for Pediatric Placebo-Controlled Trials: FDA Outcomes and Perspectives. <i>Therapeutic Innovation and Regulatory Science</i> , 2021, 55, 282-303.	1.6	6
6	Physiologically Based Pharmacokinetic Modeling Framework to Predict Neonatal Pharmacokinetics of Transplacentally Acquired Emtricitabine, Dolutegravir, and Raltegravir. <i>Clinical Pharmacokinetics</i> , 2021, 60, 795-809.	3.5	14
7	Drug Safety in Labeling for Pediatric Drug Development and Dose Selection in Submissions to the US Food and Drug Administration. <i>Journal of Clinical Pharmacology</i> , 2021, 61, S133-S140.	2.0	3
8	Methods Used for Pediatric Dose Selection in Drug Development Programs Submitted to the US FDA 2012â€2020. <i>Journal of Clinical Pharmacology</i> , 2021, 61, S28-S35.	2.0	6
9	Applying the Noninferiority Paradigm to Assess Exposureâ€Response Similarity and Dose Between Pediatric and Adult Patients. <i>Journal of Clinical Pharmacology</i> , 2021, 61, S165-S174.	2.0	3
10	Neonatal and Pediatric Dose Selection: Quo Vadis?. <i>Journal of Clinical Pharmacology</i> , 2021, 61, S7-S8.	2.0	2
11	Progress in Drug Developmentâ€Pediatric Dose Selection: Workshop Summary. <i>Journal of Clinical Pharmacology</i> , 2021, 61, S13-S21.	2.0	3
12	Evaluation of Physiologically Based Pharmacokinetic Models to Predict the Absorption of BCS Class I Drugs in Different Pediatric Age Groups. <i>Journal of Clinical Pharmacology</i> , 2021, 61, S94-S107.	2.0	1
13	Inclusion of Infants and Neonates in Pediatric Orphan Product Approvals. <i>Clinical Pharmacology and Therapeutics</i> , 2021, 110, 997-1003.	4.7	3
14	Regulatory Considerations for the Mother, Fetus and Neonate in Fetal Pharmacology Modeling. <i>Frontiers in Pediatrics</i> , 2021, 9, 698611.	1.9	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?. <i>Frontiers in Pediatrics</i> , 2021, 9, 723006.	1.9	7
16	International Coherence of Pediatric Drug Labeling for Drug Safety: Comparison of Approved Labels in Korea and the United States. <i>Clinical Pharmacology and Therapeutics</i> , 2020, 107, 530-540.	4.7	6
17	Physiologically Based Pharmacokinetic Models to Predict Maternal Pharmacokinetics and Fetal Exposure to Emtricitabine and Acyclovir. <i>Journal of Clinical Pharmacology</i> , 2020, 60, 240-255.	2.0	34
18	The RACE to Develop New Targeted Therapies for Children With CNS Tumors. <i>Clinical Pharmacology and Therapeutics</i> , 2020, 108, 434-436.	4.7	3

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19	Approaches to Dose Finding in Neonates, Illustrating the Variability between Neonatal Drug Development Programs. <i>Pharmaceutics</i> , 2020, 12, 685.	4.5	20
20	Combined Pediatric and Adult Trials Submitted to the US Food and Drug Administration 2012â€“2018. <i>Clinical Pharmacology and Therapeutics</i> , 2020, 108, 1018-1025.	4.7	15
21	Prediction of Maternal and Fetal Pharmacokinetics of Dolutegravir and Raltegravir Using Physiologically Based Pharmacokinetic Modeling. <i>Clinical Pharmacokinetics</i> , 2020, 59, 1433-1450.	3.5	16
22	Dosing Recommendations for Pediatric Patients With Renal Impairment. <i>Journal of Clinical Pharmacology</i> , 2020, 60, 1551-1560.	2.0	6
23	Exposureâ€“Response Assessment in Pediatric Drug Development Studies Submitted to the US Food and Drug Administration. <i>Clinical Pharmacology and Therapeutics</i> , 2020, 108, 90-98.	4.7	14
24	Scientific and Regulatory Considerations for an Ontogeny Knowledge Base for Pediatric Clinical Pharmacology. <i>Clinical Pharmacology and Therapeutics</i> , 2020, 107, 707-709.	4.7	3
25	Extrapolation of Adult Efficacy to Pediatric Patients With Chemotherapyâ€“Induced Nausea and Vomiting. <i>Journal of Clinical Pharmacology</i> , 2020, 60, 775-784.	2.0	3
26	The Revolution in Pediatric Drug Development and Drug Use: Therapeutic Orphans No More. <i>Journal of Pediatric Pharmacology and Therapeutics</i> , 2020, 25, 565-573.	0.5	19
27	Surrogate Endpoints in Pediatric Studies Submitted to the US FDA. <i>Clinical Pharmacology and Therapeutics</i> , 2019, 105, 555-557.	4.7	5
28	Pediatric Renal Ontogeny and Applications in Drug Development. <i>Journal of Clinical Pharmacology</i> , 2019, 59, S9-S20.	2.0	11
29	Pediatric Ontogeny: Moving From Translational Science to Drug Development. <i>Journal of Clinical Pharmacology</i> , 2019, 59, S7-S8.	2.0	4
30	Incorporating Ontogeny in Physiologically Based Pharmacokinetic Modeling to Improve Pediatric Drug Development: What We Know About Developmental Changes in Membrane Transporters. <i>Journal of Clinical Pharmacology</i> , 2019, 59, S56-S69.	2.0	23
31	Predicting the pharmacokinetics of piperacillin and tazobactam in preterm and term neonates using physiologically based pharmacokinetic modeling. <i>Computational Toxicology</i> , 2019, 12, 100104.	3.3	4
32	A Comparison of Pediatric and Adult Safety Studies for Antipsychotic and Antidepressant Drugs Submitted to the United States Food and Drug Administration. <i>Journal of Pediatrics</i> , 2019, 208, 236-242.e3.	1.8	32
33	Ontogeny equations with probability distributions for anthropomorphic measurements in preterm and term neonates and infants for use in a PBPK model. <i>Computational Toxicology</i> , 2019, 11, 101-117.	3.3	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. <i>Journal of Clinical Pharmacology</i> , 2019, 59, 1130-1143.	2.0	25
35	Renal Clearance in Newborns and Infants: Predictive Performance of Populationâ€“Based Modeling for Drug Development. <i>Clinical Pharmacology and Therapeutics</i> , 2019, 105, 1462-1470.	4.7	27
36	Dosage Considerations for Canakinumab in Children With Periodic Fever Syndromes. <i>Clinical Pharmacology and Therapeutics</i> , 2019, 106, 557-567.	4.7	14

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37	Pediatric Drug-Drug Interaction Studies: Barriers and Opportunities. <i>Clinical Pharmacology and Therapeutics</i> , 2019, 105, 1067-1070.	4.7	27
38	Primary Endpoints in Pediatric Efficacy Trials Submitted to the US FDA. <i>Journal of Clinical Pharmacology</i> , 2018, 58, 885-890.	2.0	19
39	Pediatric Drug Development: Outlook for Science-Based Innovation. <i>Clinical Pharmacology and Therapeutics</i> , 2018, 103, 376-378.	4.7	27
40	Obesity and Pediatric Drug Development. <i>Journal of Clinical Pharmacology</i> , 2018, 58, 650-661.	2.0	20
41	Pediatric Development of Molecularly Targeted Oncology Drugs. <i>Clinical Pharmacology and Therapeutics</i> , 2018, 104, 384-389.	4.7	5
42	Enrichment Strategies in Pediatric Drug Development: An Analysis of Trials Submitted to the US Food and Drug Administration. <i>Clinical Pharmacology and Therapeutics</i> , 2018, 104, 983-988.	4.7	7
43	Neonatal Safety Information Reported to the FDA During Drug Development Studies. <i>Therapeutic Innovation and Regulatory Science</i> , 2018, 52, 100-108.	1.6	27
44	Glomerular Filtration Rate Estimation Formulas for Pediatric and Neonatal Use. <i>Journal of Pediatric Pharmacology and Therapeutics</i> , 2018, 23, 424-431.	0.5	36
45	Bridging Adult Experience to Pediatrics in Oncology Drug Development. <i>Journal of Clinical Pharmacology</i> , 2017, 57, S129-S135.	2.0	5
46	Physiologically Based Pharmacokinetic Prediction of Linezolid and Emtricitabine in Neonates and Infants. <i>Clinical Pharmacokinetics</i> , 2017, 56, 383-394.	3.5	16
47	Bone Mineral Density to Assess Pediatric Bone Health in Drug Development. <i>Therapeutic Innovation and Regulatory Science</i> , 2017, 51, 756-760.	1.6	2
48	Exposure Matching for Extrapolation of Efficacy in Pediatric Drug Development. <i>Journal of Clinical Pharmacology</i> , 2016, 56, 1326-1334.	2.0	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. <i>Journal of Clinical Pharmacology</i> , 2015, 55, 1175-1183.	2.0	16
51	Adverse Event Detection and Labeling in Pediatric Drug Development: Antiretroviral Drugs. <i>Therapeutic Innovation and Regulatory Science</i> , 2015, 49, 302-309.	1.6	10
52	Drug development for pediatric neurogenic bladder dysfunction: Dosing, endpoints, and study design. <i>Journal of Clinical Pharmacology</i> , 2014, 54, 1239-1246.	2.0	5
53	Adolescent Dosing and Labeling Since the Food and Drug Administration Amendments Act of 2007. <i>JAMA Pediatrics</i> , 2013, 167, 926.	6.2	89
54	Methodological Issues in the Design of Paediatric Pharmacokinetic Studies. <i>Pharmaceutical Medicine</i> , 2012, 26, 13-22.	1.9	3

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55	Identification of Factors Affecting Tacrolimus Level and 5-Year Clinical Outcome in Kidney Transplant Patients. <i>Basic and Clinical Pharmacology and Toxicology</i> , 2012, 111, 217-223.	2.5	23
56	Translational Biomarkers: from Preclinical to Clinical a Report of 2009 AAPS/ACCP Biomarker Workshop. <i>AAPS Journal</i> , 2011, 13, 274-283.	4.4	29
57	Extrapolation of Adult Data and Other Data in Pediatric Drug-Development Programs. <i>Pediatrics</i> , 2011, 128, e1242-e1249.	2.1	259
58	Understanding the Genetic Basis for Adverse Drug Effects: The Calcineurin Inhibitors. <i>Pharmacotherapy</i> , 2010, 30, 195-209.	2.6	22
59	Update on the clinical pharmacogenomics of organ transplantation. <i>Pharmacogenomics</i> , 2010, 11, 227-236.	1.3	19
60	Pharmacogenomic Biomarker Information in Drug Labels Approved by the United States Food and Drug Administration: Prevalence of Related Drug Use. <i>Pharmacotherapy</i> , 2008, 28, 992-998.	2.6	272
61	Qualification of Biomarkers for Drug Development in Organ Transplantation. <i>American Journal of Transplantation</i> , 2008, 8, 267-270.	4.7	30
62	The impact of P-glycoprotein and Mrp2 on mycophenolic acid levels in mice. <i>Transplant Immunology</i> , 2008, 19, 192-196.	1.2	38
63	Pharmacogenomics: The Key to Improved Drug Therapy in Transplant Patients. <i>Clinics in Laboratory Medicine</i> , 2008, 28, 411-422.	1.4	11
64	Genetic Polymorphisms Impact the Risk of Acute Rejection in Pediatric Heart Transplantation: A Multi-Institutional Study. <i>Transplantation</i> , 2008, 85, 1632-1639.	1.0	56
65	A novel variant L263F in human inosine 5'-monophosphate dehydrogenase 2 is associated with diminished enzyme activity. <i>Pharmacogenetics and Genomics</i> , 2007, 17, 283-290.	1.5	47
66	Looking beneath the surface of the CYP3A5 polymorphism. <i>Pediatric Transplantation</i> , 2007, 11, 239-240.	1.0	3
67	Progress in the Direct Application of Pharmacogenomics to Patient Care: Sustaining innovation. <i>Biomolecules and Therapeutics</i> , 2007, 15, 1-6.	2.4	3
68	Impact of ABCB1 (MDR1) haplotypes on tacrolimus dosing in adult lung transplant patients who are CYP3A5 *3/*3 nonexpressors. <i>Transplant Immunology</i> , 2006, 15, 235-240.	1.2	63
69	Pharmacogenetics in Transplant Patients. <i>Therapeutic Drug Monitoring</i> , 2006, 28, 23-30.	2.0	34
70	Disparate Distribution of 16 Candidate Single Nucleotide Polymorphisms Among Racial and Ethnic Groups of Pediatric Heart Transplant Patients. <i>Transplantation</i> , 2006, 82, 1774-1780.	1.0	67
71	Ciclosporin aerosol in lung transplantation. <i>Expert Opinion on Investigational Drugs</i> , 2006, 15, 981-986.	4.1	2
72	Tacrolimus Dosing in Adult Lung Transplant Patients Is Related to Cytochrome P4503A5 Gene Polymorphism. <i>Journal of Clinical Pharmacology</i> , 2004, 44, 135-140.	2.0	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.	4.7	239
74	The MDR1 polymorphisms at exons 21 and 26 predict steroid weaning in pediatric heart transplant patients. Human Immunology, 2002, 63, 765-770.	2.4	98
75	Clinical Pharmacokinetics of Tacrolimus. Clinical Pharmacokinetics, 1995, 29, 404-430.	3.5	671
76	Clinical Pharmacokinetics in Organ Transplant Patients. Clinical Pharmacokinetics, 1989, 16, 134-161.	3.5	57
77	Clinical Pharmacokinetics of Cyclosporin. Clinical Pharmacokinetics, 1986, 11, 107-132.	3.5	431
78	Rectal thiopental versus an intramuscular cocktail for sedating children before computerized tomography. American Journal of Health-System Pharmacy, 1980, 37, 222-224.	1.0	11
79	Applications of Pharmacogenomics to Pediatric Drug Development. , 0, , 316-331.		0