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Neonatal Safety Information Reported to the FDA During Drug Development Studies

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2017, 1-9.

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27	Pediatric Drug Development: Outlook for Science-Based Innovation. <i>Clinical Pharmacology and Therapeutics</i> , 2018 , 103, 376-378	6.1	17
26	Challenges and Opportunities in the Development of Medical Therapies for Pediatric Populations and the Role of Extrapolation. <i>Clinical Pharmacology and Therapeutics</i> , 2018 , 103, 419-433	6.1	22
25	Developmental Pharmacodynamics and Modeling in Pediatric Drug Development. <i>Journal of Clinical Pharmacology</i> , 2019 , 59 Suppl 1, S87-S94	2.9	7
24	Pediatric Formulations: Knowledge Gaps Limiting the Expedited Preclinical to Clinical Translation in Children. <i>AAPS PharmSciTech</i> , 2019 , 20, 73	3.9	4
23	Questionable Industry-Sponsored Postneonatal Pediatric Studies in Slovenia. <i>Current Therapeutic Research</i> , 2019 , 90, 86-91	2.4	2
22	Pediatric melanoma-The whole (conflicts of interest) story. <i>International Journal of Women's Dermatology</i> , 2019 , 5, 110-115	2	18
21	Dynamics of Organic Anion Transporter-Mediated Tubular Secretion during Postnatal Human Kidney Development and Maturation. <i>Clinical Journal of the American Society of Nephrology: CJASN</i> , 2019 , 14, 540-548	6.9	11
20	Regulatory strategies for rare diseases under current global regulatory statutes: a discussion with stakeholders. <i>Orphanet Journal of Rare Diseases</i> , 2019 , 14, 36	4.2	26
19	The Meanings of "Pediatric Drug Development". <i>Therapeutic Innovation and Regulatory Science</i> , 2019 , 53, 767-774	1.2	15
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15	Combined Pediatric and Adult Trials Submitted to the US Food and Drug Administration 2012-2018. <i>Clinical Pharmacology and Therapeutics</i> , 2020 , 108, 1018-1025	6.1	4
14	Dosing Recommendations for Pediatric Patients With Renal Impairment. <i>Journal of Clinical Pharmacology</i> , 2020 , 60, 1551-1560	2.9	4
13	Potential implications of DMET ontogeny on the disposition of commonly prescribed drugs in neonatal and pediatric intensive care units. <i>Expert Opinion on Drug Metabolism and Toxicology</i> , 2021 , 17, 273-289	5.5	0
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11	A paradigm shift. 2021 , 27-42		

10 Introduction. **2021**, xxxix-xlix

9 Challenges at the interface of science, drug development, and drug approval beyond specific disease areas. **2021**, 271-336

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