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Reverse Translation of US Food and Drug Administration Reviews of Oncology New Molecular Entities Approved in 2011-2017: Lessons Learned for Anticancer Drug Development

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Clinical and Translational Science, 2018, 11, 123-146.

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#	Paper	IF	Citations
31	It's Time to Reverse our Thinking: The Reverse Translation Research Paradigm. <i>Clinical and Translational Science</i> , 2018 , 11, 98-99	4.9	18
30	Clinical Pharmacology of Ixazomib: The First Oral Proteasome Inhibitor. <i>Clinical Pharmacokinetics</i> , 2019 , 58, 431-449	6.2	31
29	Dose Optimization for Anticancer Drug Combinations: Maximizing Therapeutic Index via Clinical Exposure-Toxicity/Preclinical Exposure-Efficacy Modeling. <i>Clinical Cancer Research</i> , 2019 , 25, 6633-6643	12.9	11
28	Population Pharmacokinetic Modeling and Exposure-Response Assessment for the Antibody-Drug Conjugate Brentuximab Vedotin in Hodgkin's Lymphoma in the Phase III ECHELON-1 Study. <i>Clinical Pharmacology and Therapeutics</i> , 2019 , 106, 1268-1279	6.1	8
27	Model-Based Meta-Analysis: Optimizing Research, Development, and Utilization of Therapeutics Using the Totality of Evidence. <i>Clinical Pharmacology and Therapeutics</i> , 2019 , 106, 981-992	6.1	14
26	Characterizing the Sources of Pharmacokinetic Variability for TAK-117 (Serabelisib), an Investigational Phosphoinositide 3-Kinase Alpha Inhibitor: A Clinical Biopharmaceutics Study to Inform Development Strategy. <i>Clinical Pharmacology in Drug Development</i> , 2019 , 8, 637-646	2.3	5
25	The Effect of a High-Fat Meal on the Pharmacokinetics of Brigatinib, an Oral Anaplastic Lymphoma Kinase Inhibitor, in Healthy Volunteers. <i>Clinical Pharmacology in Drug Development</i> , 2019 , 8, 734-741	2.3	10
24	Model-Informed Drug Development for Ixazomib, an Oral Proteasome Inhibitor. <i>Clinical Pharmacology and Therapeutics</i> , 2019 , 105, 376-387	6.1	6
23	Population Pharmacokinetics of Brentuximab Vedotin in Adult and Pediatric Patients With Relapsed/Refractory Hematologic Malignancies: Model-Informed Hypothesis Generation for Pediatric Dosing Regimens. <i>Journal of Clinical Pharmacology</i> , 2020 , 60, 1585-1597	2.9	2
22	Brigatinib Dose Rationale in Anaplastic Lymphoma Kinase-Positive Non-Small Cell Lung Cancer: Exposure-Response Analyses of Pivotal ALTA Study. <i>CPT: Pharmacometrics and Systems Pharmacology</i> , 2020 , 9, 718-730	4.5	7
21	Personalized biomedicine in cancer: from traditional therapy to sustainable healthcare. 2020 , 441-457		
20	Phase 1 Study to Evaluate the Effect of the Investigational Anticancer Agent Sapanisertib on the QTc Interval in Patients With Advanced Solid Tumors. <i>Clinical Pharmacology in Drug Development</i> , 2020 , 9, 876-888	2.3	4
19	Pharmacokinetic Profile of Gilteritinib: A Novel FLT-3 Tyrosine Kinase Inhibitor. <i>Clinical Pharmacokinetics</i> , 2020 , 59, 1273-1290	6.2	15
18	Clinical Pharmacology Modeling and Simulation in Drug Development. 2021 , 243-256		
17	Phase I study assessing the mass balance, pharmacokinetics, and excretion of [C]-pevonedistat, a NEDD8-activating enzyme inhibitor in patients with advanced solid tumors. <i>Investigational New Drugs</i> , 2021 , 39, 488-498	4.3	4
16	Population Pharmacokinetics of Brigatinib in Healthy Volunteers and Patients With Cancer. <i>Clinical Pharmacokinetics</i> , 2021 , 60, 235-247	6.2	6
15	QT Prolongation Risk Assessment in Oncology: Lessons Learned From Small-Molecule New Drug Applications Approved During 2011-2019. <i>Journal of Clinical Pharmacology</i> , 2021 , 61, 1106-1117	2.9	0

14	Essential (and Largely Untaught) Skills for Clinical Pharmacology in Oncology Drug Development. <i>Clinical Pharmacology and Therapeutics</i> , 2021 ,	6.1	
13	Effects of Itraconazole and Rifampin on the Pharmacokinetics of Mobocertinib (TAK-788), an Oral Epidermal Growth Factor Receptor Inhibitor, in Healthy Volunteers. <i>Clinical Pharmacology in Drug Development</i> , 2021 , 10, 1044-1053	2.3	4
12	Single-Dose Pharmacokinetics and Tolerability of the Oral Epidermal Growth Factor Receptor Inhibitor Mobocertinib (TAK-788) in Healthy Volunteers: Low-Fat Meal Effect and Relative Bioavailability of 2 Capsule Products. <i>Clinical Pharmacology in Drug Development</i> , 2021 , 10, 1028-1043	2.3	3
11	Population Pharmacokinetics of TAK-931, a Cell Division Cycle 7 Kinase Inhibitor, in Patients With Advanced Solid Tumors. <i>Journal of Clinical Pharmacology</i> , 2021 ,	2.9	1
10	Assessment of structural peculiarities of glaziovianin A interaction with human β -tubulins. <i>Faktori Eksperimental Noi Evolucii Organizmiv</i> , 22, 340-344		
9	Population Pharmacokinetic and Exposure-Response Analyses From ALTA-1L: Model-Based Analyses Supporting the Brigatinib Dose in ALK-Positive NSCLC.. <i>Clinical and Translational Science</i> , 2022 ,	4.9	1
8	Assessment of Effects of Investigational TAK-931, an Oral Cell Division Cycle 7 Kinase Inhibitor on the QTc Intervals in Patients With Advanced Solid Tumors.. <i>Clinical Pharmacology in Drug Development</i> , 2022 ,	2.3	
7	ExposureResponse analyses for the MET inhibitor tepotinib including patients in the pivotal VISION trial: support for dosage recommendations. <i>Cancer Chemotherapy and Pharmacology</i> ,	3.5	
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5	Clinical pharmacology information in regulatory submissions and labeling: A comparative analysis of orphan and non-orphan drugs approved by the FDA.		o
4	Effect of Pevonedistat, an Investigational NEDD8-Activating Enzyme Inhibitor, on the QTc Interval in Patients With Advanced Solid Tumors.		o
3	US FDA Postmarketing Requirements and Commitments: A Systematic Assessment of Clinical Pharmacology Studies and Their Impact on US FDA Prescribing Information.		o
2	Proteomic quantification of receptor tyrosine kinases involved in the development and progression of colorectal cancer liver metastasis. 13,		o
1	A comprehensive regulatory and industry review of modeling and simulation practices in oncology clinical drug development.		o