

Shein-Chung Chow

List of Publications by Year in descending order

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137
papers

2,997
citations

236833

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243529

44
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144
all docs

144
docs citations

144
times ranked

2907
citing authors

#	ARTICLE	IF	CITATIONS
1	Innovative Design and Analysis for PK/PD Biosimilar Bridging Studies with Multiple References. AAPS Journal, 2022, 24, 3.	2.2	0
2	Current Issues in Analytical Similarity Assessment. Statistics in Biopharmaceutical Research, 2021, 13, 203-209.	0.6	2
3	Sample size re-estimation in clinical trials. Statistics in Medicine, 2021, 40, 6133-6149.	0.8	5
4	The use of real-world data/evidence in regulatory submissions. Contemporary Clinical Trials, 2021, 109, 106521.	0.8	4
5	Review of current controversial issues in clinical trials. Annals of General Psychiatry, 2021, 34, e100540.	1.1	2
6	Tenofovir versus entecavir in lowering the risk of hepatocellular carcinoma development in patients with chronic hepatitis B: a critical systematic review and meta-analysis. Hepatology International, 2020, 14, 105-114.	1.9	31
7	A Time-Response Measure to Assess Clinical Equivalence in Rheumatoid Arthritis: An Assessment Using Data From Clinical Trials of Biosimilars. Statistics in Biopharmaceutical Research, 2020, , 1-13.	0.6	0
8	Statistical Evaluation of Clinical Trials Under COVID-19 Pandemic. Therapeutic Innovation and Regulatory Science, 2020, 54, 1551-1556.	0.8	2
9	Unified approaches to assessing treatment effect of traditional Chinese medicine based on health profiles. Journal of Biopharmaceutical Statistics, 2020, 30, 564-573.	0.4	0
10	Innovative design and analysis for rare disease drug development. Journal of Biopharmaceutical Statistics, 2020, 30, 537-549.	0.4	12
11	Some thoughts on the QR method for analytical similarity evaluation. Journal of Biopharmaceutical Statistics, 2020, 30, 521-536.	0.4	2
12	Practical Issues in Clinical Inspection Process. Therapeutic Innovation and Regulatory Science, 2019, 53, 374-380.	0.8	0
13	Design and Analysis of Biosimilar Switching Studies. Pharmaceutical Medicine, 2019, 33, 379-388.	1.0	0
14	Interim analysis of binary outcome data in clinical trials: a comparison of five estimators. Journal of Biopharmaceutical Statistics, 2019, 29, 400-410.	0.4	0
15	Simultaneous confidence interval methods for analytical similarity assessment. Journal of Biopharmaceutical Statistics, 2019, 29, 920-940.	0.4	3
16	Statistical considerations for rare diseases drug development. Journal of Biopharmaceutical Statistics, 2019, 29, 874-886.	0.4	6
17	The use of 95% CI or 90% CI for drug product development – a controversial issue?. Journal of Biopharmaceutical Statistics, 2019, 29, 834-844.	0.4	4
18	Probability monitoring procedures for sample size determination. Journal of Biopharmaceutical Statistics, 2019, 29, 887-896.	0.4	4

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19	Criteria for dose-finding in two-stage seamless adaptive design. Journal of Biopharmaceutical Statistics, 2019, 29, 908-919.	0.4	2
20	Innovative Thinking on Endpoint Selection in Clinical Trials. Journal of Biopharmaceutical Statistics, 2019, 29, 941-951.	0.4	0
21	Demonstrating effectiveness or demonstrating not ineffectiveness – A potential solution for rare disease drug product development?. Journal of Biopharmaceutical Statistics, 2019, 29, 897-907.	0.4	8
22	On sample size requirement for analytical similarity assessment. Journal of Biopharmaceutical Statistics, 2018, 28, 1143-1159.	0.4	0
23	On evaluation of consistency in multi-regional clinical trials. Journal of Biopharmaceutical Statistics, 2018, 28, 840-856.	0.4	4
24	Design and Analysis of Biosimilar Studies. ICSA Book Series in Statistics, 2018, , 277-305.	0.0	0
25	Analysis of Two-Stage Adaptive Trial Designs. ICSA Book Series in Statistics, 2018, , 217-241.	0.0	0
26	On the establishment of equivalence acceptance criterion in analytical similarity assessment. Journal of Biopharmaceutical Statistics, 2017, 27, 206-212.	0.4	7
27	Differences in Phenotypes and Liver Transplantation Outcomes by Age Group in Patients with Primary Sclerosing Cholangitis. Digestive Diseases and Sciences, 2017, 62, 3200-3209.	1.1	10
28	Complementary and Alternative Medicine Use in United States Adults With Liver Disease. Journal of Clinical Gastroenterology, 2017, 51, 564-570.	1.1	20
29	On assessing bioequivalence and interchangeability between generics based on indirect comparisons. Statistics in Medicine, 2017, 36, 2978-2993.	0.8	2
30	Outcomes of liver retransplantation in patients with primary sclerosing cholangitis. Liver Transplantation, 2017, 23, 769-780.	1.3	26
31	On hybrid parallel – crossover designs for assessing drug interchangeability of biosimilar products. Journal of Biopharmaceutical Statistics, 2017, 27, 265-271.	0.4	5
32	Assessing bioequivalence and drug interchangeability. Journal of Biopharmaceutical Statistics, 2017, 27, 272-281.	0.4	6
33	Sample size requirement in analytical studies for similarity assessment. Journal of Biopharmaceutical Statistics, 2017, 27, 233-238.	0.4	5
34	On the evaluation of reliability, repeatability, and reproducibility of instrumental evaluation methods and measurement systems. Journal of Biopharmaceutical Statistics, 2017, 27, 331-337.	0.4	1
35	Statistical evaluation of the scaled criterion for drug interchangeability. Journal of Biopharmaceutical Statistics, 2017, 27, 282-292.	0.4	4
36	Clinical endpoints and adaptive clinical trials in precirrhotic nonalcoholic steatohepatitis: Facilitating development approaches for an emerging epidemic. Hepatology Communications, 2017, 1, 577-585.	2.0	41

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37	Analytical similarity assessment. Wiley Interdisciplinary Reviews: Computational Statistics, 2017, 9, e1407.	2.1	2
38	Clinical Performance of Prediction Rules and Nasogastric Lavage for the Evaluation of Upper Gastrointestinal Bleeding: A Retrospective Observational Study. Gastroenterology Research and Practice, 2017, 2017, 1-8.	0.7	5
39	Female gender lost protective effect against disease progression in elderly patients with chronic hepatitis B. Scientific Reports, 2016, 6, 37498.	1.6	13
40	Analytical Similarity Assessment in Biosimilar Studies. AAPS Journal, 2016, 18, 670-677.	2.2	29
41	On sample size estimation and re-estimation adjusting for variability in confirmatory trials. Journal of Biopharmaceutical Statistics, 2016, 26, 44-54.	0.4	2
42	Coronary artery disease risk reduction in HIV-infected persons: a comparative analysis. AIDS Care - Psychological and Socio-Medical Aspects of AIDS/HIV, 2016, 28, 475-482.	0.6	19
43	Some thoughts on drug interchangeability. Journal of Biopharmaceutical Statistics, 2016, 26, 178-186.	0.4	8
44	Confidence Region Approach for Assessing Bioequivalence and Biosimilarity Accounting for Heterogeneity of Variability. Journal of Probability and Statistics, 2015, 2015, 1-13.	0.3	0
45	Independent data monitoring committees: Preparing a path for the future. American Heart Journal, 2014, 168, 135-141.e1.	1.2	16
46	Scientific Factors and Current Issues in Biosimilar Studies. Journal of Biopharmaceutical Statistics, 2014, 24, 1138-1153.	0.4	8
47	Nonparametric Tests for Evaluation of Biosimilarity in Variability of Follow-on Biologics. Journal of Biopharmaceutical Statistics, 2014, 24, 1239-1253.	0.4	6
48	Adaptive Clinical Trial Design. Annual Review of Medicine, 2014, 65, 405-415.	5.0	113
49	Bioavailability and bioequivalence in drug development. Wiley Interdisciplinary Reviews: Computational Statistics, 2014, 6, 304-312.	2.1	125
50	Assessing biosimilarity and interchangeability of biosimilar products. Statistics in Medicine, 2013, 32, 361-363.	0.8	13
51	Statistical methods for assessing interchangeability of biosimilars. Statistics in Medicine, 2013, 32, 442-448.	0.8	20
52	Impact of variability on the choice of biosimilarity limits in assessing follow-on biologics. Statistics in Medicine, 2013, 32, 424-433.	0.8	10
53	An adapted F -test for homogeneity of variability in follow-on biological products. Statistics in Medicine, 2013, 32, 415-423.	0.8	8
54	The evaluation of biosimilarity index based on reproducibility probability for assessing follow-on biologics. Statistics in Medicine, 2013, 32, 406-414.	0.8	23

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55	Scientific considerations for assessing biosimilar products. <i>Statistics in Medicine</i> , 2013, 32, 370-381.	0.8	26
56	Comments on the FDA draft guidance on biosimilar products. <i>Statistics in Medicine</i> , 2013, 32, 364-369.	0.8	11
57	Statistical assessment of biosimilarity based on relative distance between follow-on biologics. <i>Statistics in Medicine</i> , 2013, 32, 382-392.	0.8	24
58	Sample Size and Data Monitoring for Clinical Trials With Extremely Low Incidence Rates. <i>Therapeutic Innovation and Regulatory Science</i> , 2013, 47, 438-446.	0.8	1
59	Statistical Considerations in Biosimilar Assessment Using Biosimilarity Index. <i>Journal of Bioequivalence & Bioavailability</i> , 2013, 05, 209-214.	0.1	5
60	On the Independence of Data Monitoring Committee in Adaptive Design Clinical Trials. <i>Journal of Biopharmaceutical Statistics</i> , 2012, 22, 853-867.	0.4	29
61	On Sample Size Calculation for Comparing Survival Curves Under General Hypothesis Testing. <i>Journal of Biopharmaceutical Statistics</i> , 2012, 22, 485-495.	0.4	15
62	Statistical Methods for Bridging Studies. <i>Journal of Biopharmaceutical Statistics</i> , 2012, 22, 903-915.	0.4	9
63	On the Regulatory Approval Pathway of Biosimilar Products. <i>Pharmaceuticals</i> , 2012, 5, 353-368.	1.7	78
64	Authors' reply to the letter to the editor by L. Chen and Y. X. Liu. <i>Pharmaceutical Statistics</i> , 2012, 11, 343-345.	0.7	0
65	Imputation Method Adjusted for Covariates for Nonrespondents in Instruments with Applications. <i>Journal of Biopharmaceutical Statistics</i> , 2011, 21, 342-354.	0.4	1
66	Benefits, challenges and obstacles of adaptive clinical trial designs. <i>Orphanet Journal of Rare Diseases</i> , 2011, 6, 79.	1.2	47
67	Sample size calculations for clinical trials. <i>Wiley Interdisciplinary Reviews: Computational Statistics</i> , 2011, 3, 414-427.	2.1	21
68	Some Controversial Issues in Clinical Trials. <i>Drug Information Journal</i> , 2011, 45, 163-174.	0.5	2
69	A Note on Special Articles on Adaptive Clinical Trial Designs. <i>Journal of Biopharmaceutical Statistics</i> , 2010, 20, 1088-1089.	0.4	5
70	Authors' Response to "Comment on: Cheng, Chow, Burt, and Cosmatos (2008). Statistical Assessment of QT/QTc Prolongation Based on Maximum of Correlated Normal Random Variables". <i>Journal of Biopharmaceutical Statistics</i> , 2010, 20, 1074-1074.	0.4	0
71	The use of complementary and alternative medicine by patients with chronic hepatitis C. <i>Complementary Therapies in Clinical Practice</i> , 2010, 16, 124-131.	0.7	20
72	Bridging Diversity. <i>Pharmaceutical Medicine</i> , 2010, 24, 349-362.	1.0	8

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73	Test for Ordered Categorical Data. , 2010, , 1338-1342.		0
74	Clinical Strategy for Study Endpoint Selection. , 2010, , 19-1-19-15.		0
75	Overview of Adaptive Design Methods in Clinical Trials. , 2010, , 1-1-1-19.		1
76	Statistical Test for Evaluation of Biosimilarity in Variability of Follow-On Biologics. Journal of Biopharmaceutical Statistics, 2009, 20, 75-89.	0.4	13
77	Statistical Validation of Traditional Chinese Diagnostic Procedures. Drug Information Journal, 2009, 43, 83-95.	0.5	3
78	A Comparison of Moment-Based and Probability-Based Criteria for Assessment of Follow-On Biologics. Journal of Biopharmaceutical Statistics, 2009, 20, 31-45.	0.4	30
79	Deviations from linearity in statistical evaluation of linearity in assay validation. Journal of Chemometrics, 2009, 23, 487-494.	0.7	6
80	Statistical Methods for Assessment of Biosimilarity Using Biomarker Data. Journal of Biopharmaceutical Statistics, 2009, 20, 90-105.	0.4	6
81	Statistical Assessment of Biosimilar Products. Journal of Biopharmaceutical Statistics, 2009, 20, 10-30.	0.4	31
82	Sample size calculation for the log-rank tests for multi-arm trials with a control. Journal of the Korean Statistical Society, 2008, 37, 11-22.	0.3	5
83	Adaptive design methods in clinical trials – a review. Orphanet Journal of Rare Diseases, 2008, 3, 11.	1.2	346
84	Statistical Tests for One-way/Two-way Translation in Translational Medicine. Journal of the Formosan Medical Association, 2008, 107, S43-S51.	0.8	1
85	On Two-stage Seamless Adaptive Design in Clinical Trials. Journal of the Formosan Medical Association, 2008, 107, S52-S60.	0.8	17
86	Statistical Methods in Translational Medicine. Journal of the Formosan Medical Association, 2008, 107, S61-S73.	0.8	4
87	On Power and Sample Size Calculation for QT Studies with Recording Replicates at Given Time Point. Journal of Biopharmaceutical Statistics, 2008, 18, 483-493.	0.4	20
88	A Two-Stage Design for Drug Screening Trials Based on Continuous Endpoints. Drug Information Journal, 2008, 42, 253-262.	0.5	5
89	Statistical Test for Ordered Categorical Data in Clinical Trials. Drug Information Journal, 2008, 42, 617-624.	0.5	2
90	Statistical Analysis for Two-Stage Seamless Design with Different Study Endpoints. Journal of Biopharmaceutical Statistics, 2007, 17, 1163-1176.	0.4	26

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91	Adaptive Group Sequential Test for Clinical Trials with Changing Patient Population. Journal of Biopharmaceutical Statistics, 2007, 17, 1227-1238.	0.4	20
92	An Alternative Approach for the Assessment of Bioequivalence Between Two Formulations of a Drug. Biometrical Journal, 2007, 32, 969-976.	0.6	20
93	Variable screening in predicting clinical outcome with high-dimensional microarrays. Journal of Multivariate Analysis, 2007, 98, 1529-1538.	0.5	12
94	Stability analysis for drugs with multiple active ingredients. Statistics in Medicine, 2007, 26, 1512-1517.	0.8	6
95	Statistical Quality Control Process for Traditional Chinese Medicine. Journal of Biopharmaceutical Statistics, 2006, 16, 861-874.	0.4	20
96	Editor's Note—JBS Is now an SCI Journal. Journal of Biopharmaceutical Statistics, 2006, 16, 273-274.	0.4	0
97	On Traditional Chinese Medicine Clinical Trials. Drug Information Journal, 2006, 40, 395-406.	0.5	13
98	On non-inferiority margin and statistical tests in active control trials. Statistics in Medicine, 2006, 25, 1101-1113.	0.8	60
99	Statistical inference for cancer trials with treatment switching. Statistics in Medicine, 2005, 24, 1783-1790.	0.8	37
100	Inference for Clinical Trials with Some Protocol Amendments. Journal of Biopharmaceutical Statistics, 2005, 15, 659-666.	0.4	31
101	Statistical Consideration of Adaptive Methods in Clinical Development. Journal of Biopharmaceutical Statistics, 2005, 15, 575-591.	0.4	105
102	A Hybrid Bayesian Adaptive Design for Dose Response Trials. Journal of Biopharmaceutical Statistics, 2005, 15, 677-691.	0.4	20
103	Cross-Validation for Linear Model with Unequal Variances in Genomic Analysis. Journal of Biopharmaceutical Statistics, 2004, 14, 723-739.	0.4	6
104	ON SAMPLE SIZE CALCULATION BASED ON ODDS RATIO IN CLINICAL TRIALS. Journal of Biopharmaceutical Statistics, 2002, 12, 471-483.	0.4	39
105	ASSESSING SENSITIVITY AND SIMILARITY IN BRIDGING STUDIES. Journal of Biopharmaceutical Statistics, 2002, 12, 385-400.	0.4	77
106	A note on statistical methods for assessing therapeutic equivalence. Contemporary Clinical Trials, 2002, 23, 515-520.	2.0	27
107	Individual bioequivalence testing under 2 ⁿ —3 designs. Statistics in Medicine, 2002, 21, 629-648.	0.8	29
108	Reproducibility probability in clinical trials. Statistics in Medicine, 2002, 21, 1727-1742.	0.8	87

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109	A practical approach for comparing means of two groups without equal variance assumption. <i>Statistics in Medicine</i> , 2002, 21, 3137-3151.	0.8	19
110	Individual Bioequivalence—A Review of the FDA Draft Guidance. <i>Drug Information Journal</i> , 1999, 33, 435-444.	0.5	24
111	Some thoughts on individual bioequivalence. <i>Journal of Biopharmaceutical Statistics</i> , 1997, 7, 41-48.	0.4	15
112	Pharmaceutical Validation and Process Controls in Drug Development. <i>Drug Information Journal</i> , 1997, 31, 1195-1201.	0.5	7
113	Good Statistics Practice in the Drug Development and Regulatory Approval Process. <i>Drug Information Journal</i> , 1997, 31, 1157-1166.	0.5	7
114	Guest Editor's Note: Practical and Regulatory Issues on New Drug, New Dosage Form, and Generic Drug Development. <i>Drug Information Journal</i> , 1997, 31, 1145-1147.	0.5	0
115	A two one-sided tests procedure for assessment of individual bioequivalence. <i>Journal of Biopharmaceutical Statistics</i> , 1997, 7, 49-61.	0.4	20
116	Statistical Evaluation of Similarity Factor f_2 as a Criterion for Assessment of Similarity Between Dissolution Profiles. <i>Drug Information Journal</i> , 1997, 31, 1255-1271.	0.5	33
117	Guest editor's note: recent issues in bioequivalence trials. <i>Journal of Biopharmaceutical Statistics</i> , 1997, 7, 1-3.	0.4	3
118	Meta-analysis for bioequivalence review. <i>Journal of Biopharmaceutical Statistics</i> , 1997, 7, 97-111.	0.4	30
119	Statistical comparison between dissolution profiles of drug products. <i>Journal of Biopharmaceutical Statistics</i> , 1997, 7, 241-258.	0.4	38
120	A note on sample size determination for bioequivalence studies with high-order crossover designs. <i>Journal of Pharmacokinetics and Pharmacodynamics</i> , 1997, 25, 753-765.	0.6	14
121	STATISTICAL METHODS FOR TWO-SEQUENCE THREE-PERIOD CROSS-OVER DESIGNS WITH INCOMPLETE DATA. <i>Statistics in Medicine</i> , 1997, 16, 1031-1039.	0.8	21
122	A Confidence Region Approach for Assessing Equivalence in Variability of Bioavailability. <i>Biometrical Journal</i> , 1996, 38, 475-487.	0.6	4
123	Statistical Issues on the FDA Conjugated Estrogen Tablets Bioequivalence Guidance. <i>Drug Information Journal</i> , 1996, 30, 881-889.	0.5	10
124	On likelihood distance for outliers detection. <i>Journal of Biopharmaceutical Statistics</i> , 1995, 5, 307-322.	0.4	6
125	On model selection for standard curve in assay development. <i>Journal of Biopharmaceutical Statistics</i> , 1995, 5, 285-296.	0.4	6
126	Guest Editor's Note: Bioavailability and Bioequivalence. <i>Drug Information Journal</i> , 1995, 29, 793-794.	0.5	2

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127	Replicated Crossover Designs in Bioavailability and Bioequivalence Trials. Drug Information Journal, 1995, 29, 871-884.	0.5	4
128	Current Issues in Bioequivalence Trials. Drug Information Journal, 1995, 29, 795-804.	0.5	29
129	On statistical characteristics of quality of life assessment. Journal of Biopharmaceutical Statistics, 1994, 4, 1-17.	0.4	16
130	Sample size determination for the two one-sided tests procedure in bioequivalence. Journal of Pharmacokinetics and Pharmacodynamics, 1992, 20, 101-104.	0.6	95
131	A Related Problem in Bioavailability/Bioequivalence Studies – Estimation of the Intrasubject Variability With a Common CV. Biometrical Journal, 1990, 32, 597-607.	0.6	8
132	Scientific factors for assessing biosimilarity and drug interchangeability of follow-on biologics. Biosimilars (Auckland, New Zealand), 0, Volume 1, 13-26.	0.4	23
133	Challenging issues in assessing analytical similarity in biosimilar studies. Biosimilars (Auckland, New Zealand), 0, Volume 1, 13-26.	0.4	17
134	Sample Size Calculations in Clinical Research: Third Edition. , 0, , .		215
135	Design and Analysis of Bioavailability and Bioequivalence Studies. , 0, , .		86
136	Adaptive Design Methods in Clinical Trials. , 0, , .		61
137	Controversial Statistical Issues in Clinical Trials. , 0, , .		8