Shein-Chung Chow

List of Publications by Year
in descending order

137	2,997	236833	243529
papers	citations	25 h-index	44 g-index

144	144	144	2907
all docs	docs citations	times ranked	citing authors

#	Article	IF	Citations
1	Adaptive design methods in clinical trials â€“ a review. Orphanet Journal of Rare Diseases, 2008, 3, 11.	1.2	346
2	Sample Size Calculations in Clinical Research: Third Edition. , 0, , .		215
3	Bioavailability and bioequivalence in drug development. Wiley Interdisciplinary Reviews: Computational Statistics, 2014, 6, 304-312.	2.1	125
4	Adaptive Clinical Trial Design. Annual Review of Medicine, 2014, 65, 405-415.	5.0	113
5	Statistical Consideration of Adaptive Methods in Clinical Development. Journal of Biopharmaceutical Statistics, 2005, 15, 575-591.	0.4	105
6	Sample size determination for the two one-sided tests procedure in bioequivalence. Journal of Pharmacokinetics and Pharmacodynamics, 1992, 20, 101-104.	0.6	95
7	Reproducibility probability in clinical trials. Statistics in Medicine, 2002, 21, 1727-1742.	0.8	87
8	Design and Analysis of Bioavailability and Bioequivalence Studies. , 0, , .		86
9	On the Regulatory Approval Pathway of Biosimilar Products. Pharmaceuticals, 2012, 5, 353-368.	1.7	78
10	ASSESSING SENSITIVITY AND SIMILARITY IN BRIDGING STUDIES. Journal of Biopharmaceutical Statistics, 2002, 12, 385-400.	0.4	77
11	Adaptive Design Methods in Clinical Trials. , 0, , .		61
12	On non-inferiority margin and statistical tests in active control trials. Statistics in Medicine, 2006, 25, 1101-1113.	0.8	60
13	Benefits, challenges and obstacles of adaptive clinical trial designs. Orphanet Journal of Rare Diseases, 2011, 6, 79.	1.2	47
14	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
15	ON SAMPLE SIZE CALCULATION BASED ON ODDS RATIO IN CLINICAL TRIALS. Journal of Biopharmaceutical Statistics, 2002, 12, 471-483.	0.4	39
16	Statistical comparison between dissolution profiles of drug products. Journal of Biopharmaceutical Statistics, 1997, 7, 241-258.	0.4	38
17	Statistical inference for cancer trials with treatment switching. Statistics in Medicine, 2005, 24, 1783-1790.	0.8	37
18	Statistical Evaluation of Similarity Factor f2 as a Criterion for Assessment of Similarity Between Dissolution Profiles. Drug Information Journal, 1997, 31, 1255-1271.	0.5	33

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19	Inference for Clinical Trials with Some Protocol Amendments. Journal of Biopharmaceutical Statistics, 2005, 15, 659-666.	0.4	31
20	Statistical Assessment of Biosimilar Products. Journal of Biopharmaceutical Statistics, 2009, 20, 10-30.	0.4	31
21	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
22	Meta-analysis for bioequivalence review. Journal of Biopharmaceutical Statistics, 1997, 7, 97-111.	0.4	30
23	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
24	Current Issues in Bioequivalence Trials. Drug Information Journal, 1995, 29, 795-804.	0.5	29
25	Individual bioequivalence testing under 2Ã—3 designs. Statistics in Medicine, 2002, 21, 629-648.	0.8	29
26	On the Independence of Data Monitoring Committee in Adaptive Design Clinical Trials. Journal of Biopharmaceutical Statistics, 2012, 22, 853-867.	0.4	29
27	Analytical Similarity Assessment in Biosimilar Studies. AAPS Journal, 2016, 18, 670-677.	2.2	29
28	A note on statistical methods for assessing therapeutic equivalence. Contemporary Clinical Trials, 2002, 23, 515-520.	2.0	27
29	Statistical Analysis for Two-Stage Seamless Design with Different Study Endpoints. Journal of Biopharmaceutical Statistics, 2007, 17, 1163-1176.	0.4	26
30	Scientific considerations for assessing biosimilar products. Statistics in Medicine, 2013, 32, 370-381.	0.8	26
31	Outcomes of liver retransplantation in patients with primary sclerosing cholangitis. Liver Transplantation, 2017, 23, 769-780.	1.3	26
32	Individual Bioequivalenceâ€”A Review of the FDA Draft Guidance. Drug Information Journal, 1999, 33, 435-444.	0.5	24
33	Statistical assessment of biosimilarity based on relative distance between follow-on biologics. Statistics in Medicine, 2013, 32, 382-392.	0.8	24
34	Scientific factors for assessing biosimilarity and drug interchangeability of follow-on biologics. Biosimilars (Auckland, New Zealand), 0, Volume 1, 13-26.	0.4	23
35	The evaluation of biosimilarity index based on reproducibility probability for assessing followâ€on biologics. Statistics in Medicine, 2013, 32, 406-414.	0.8	23
36	STATISTICAL METHODS FOR TWO-SEQUENCE THREE-PERIOD CROSS-OVER DESIGNS WITH INCOMPLETE DATA. Statistics in Medicine, 1997, 16, 1031-1039.	0.8	21

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37	Sample size calculations for clinical trials. Wiley Interdisciplinary Reviews: Computational Statistics, 2011, 3, 414-427.	2.1	21
38	A two one-sided tests procedure for assessment of individual bioequivalence. Journal of Biopharmaceutical Statistics, 1997, 7, 49-61.	0.4	20
39	A Hybrid Bayesian Adaptive Design for Dose Response Trials. Journal of Biopharmaceutical Statistics, 2005, 15, 677-691.	0.4	20
40	Statistical Quality Control Process for Traditional Chinese Medicine. Journal of Biopharmaceutical Statistics, 2006, 16, 861-874.	0.4	20
41	Adaptive Group Sequential Test for Clinical Trials with Changing Patient Population. Journal of Biopharmaceutical Statistics, 2007, 17, 1227-1238.	0.4	20
42	An Alternative Approach for the Assessment of Bioequivalence Between Two Formulations of a Drug. Biometrical Journal, 2007, 32, 969-976.	0.6	20
43	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
44	The use of complementary and alternative medicine by patients with chronic hepatitis C. Complementary Therapies in Clinical Practice, 2010, 16, 124-131.	0.7	20
45	Statistical methods for assessing interchangeability of biosimilars. Statistics in Medicine, 2013, 32, 442-448.	0.8	20
46	Complementary and Alternative Medicine Use in United States Adults With Liver Disease. Journal of Clinical Gastroenterology, 2017, 51, 564-570.	1.1	20
47	A practical approach for comparing means of two groups without equal variance assumption. Statistics in Medicine, 2002, 21, 3137-3151.	0.8	19
48	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
49	On Two-stage Seamless Adaptive Design in Clinical Trials. Journal of the Formosan Medical Association, 2008, 107, S52-S60.	0.8	17
50	Challenging issues in assessing analytical similarity in biosimilar studies. Biosimilars (Auckland, New) Tj ETQq0 0 0 rgBT /Overlock 10 Tf 5	0.4	17
51	On statistical characteristics of quality of life assessment. Journal of Biopharmaceutical Statistics, 1994, 4, 1-17.	0.4	16
52	Independent data monitoring committees: Preparing a path for the future. American Heart Journal, 2014, 168, 135-141.e1.	1.2	16
53	Some thoughts on individual bioequivalence. Journal of Biopharmaceutical Statistics, 1997, 7, 41-48.	0.4	15
54	On Sample Size Calculation for Comparing Survival Curves Under General Hypothesis Testing. Journal of Biopharmaceutical Statistics, 2012, 22, 485-495.	0.4	15

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55	A note on sample size determination for bioequivalence studies with high-order crossover designs. Journal of Pharmacokinetics and Pharmacodynamics, 1997, 25, 753-765.	0.6	14
56	On Traditional Chinese Medicine Clinical Trials. Drug Information Journal, 2006, 40, 395-406.	0.5	13
57	Statistical Test for Evaluation of Biosimilarity in Variability of Follow-On Biologics. Journal of Biopharmaceutical Statistics, 2009, 20, 75-89.	0.4	13
58	Assessing biosimilarity and interchangeability of biosimilar products. Statistics in Medicine, 2013, 32, 361-363.	0.8	13
59	Female gender lost protective effect against disease progression in elderly patients with chronic hepatitis B. Scientific Reports, 2016, 6, 37498.	1.6	13
60	Variable screening in predicting clinical outcome with high-dimensional microarrays. Journal of Multivariate Analysis, 2007, 98, 1529-1538.	0.5	12
61	Innovative design and analysis for rare disease drug development. Journal of Biopharmaceutical Statistics, 2020, 30, 537-549.	0.4	12
62	Comments on the FDA draft guidance on biosimilar products. Statistics in Medicine, 2013, 32, 364-369.	0.8	11
63	Statistical Issues on the FDA Conjugated Estrogen Tablets Bioequivalence Guidance. Drug Information Journal, 1996, 30, 881-889.	0.5	10
64	Impact of variability on the choice of biosimilarity limits in assessing followâ€on biologics. Statistics in Medicine, 2013, 32, 424-433.	0.8	10
65	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
66	Statistical Methods for Bridging Studies. Journal of Biopharmaceutical Statistics, 2012, 22, 903-915.	0.4	9
67	A Related Problem in Bioavailability/Bioequivalence Studies â€" Estimation of the Intrasubject Variability With a Common CV. Biometrical Journal, 1990, 32, 597-607.	0.6	8
68	Bridging Diversity. Pharmaceutical Medicine, 2010, 24, 349-362.	1.0	8
69	An adapted Fâ€test for homogeneity of variability in followâ€on biological products. Statistics in Medicine, 2013, 32, 415-423.	0.8	8
70	Scientific Factors and Current Issues in Biosimilar Studies. Journal of Biopharmaceutical Statistics, 2014, 24, 1138-1153.	0.4	8
71	Some thoughts on drug interchangeability. Journal of Biopharmaceutical Statistics, 2016, 26, 178-186.	0.4	8
72	Demonstrating effectiveness or demonstrating not ineffectiveness â€" A potential solution for rare disease drug product development?. Journal of Biopharmaceutical Statistics, 2019, 29, 897-907.	0.4	8

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73	Controversial Statistical Issues in Clinical Trials. , 0, , .		8
74	Pharmaceutical Validation and Process Controls in Drug Development. Drug Information Journal, 1997, 31, 1195-1201.	0.5	7
75	Good Statistics Practice in the Drug Development and Regulatory Approval Process. Drug Information Journal, 1997, 31, 1157-1166.	0.5	7
76	On the establishment of equivalence acceptance criterion in analytical similarity assessment. Journal of Biopharmaceutical Statistics, 2017, 27, 206-212.	0.4	7
77	On likelihood distance for outliers detection. Journal of Biopharmaceutical Statistics, 1995, 5, 307-322.	0.4	6
78	On model selection for standard curve in assay development. Journal of Biopharmaceutical Statistics, 1995, 5, 285-296.	0.4	6
79	Cross-Validation for Linear Model with Unequal Variances in Genomic Analysis. Journal of Biopharmaceutical Statistics, 2004, 14, 723-739.	0.4	6
80	Stability analysis for drugs with multiple active ingredients. Statistics in Medicine, 2007, 26, 1512-1517.	0.8	6
81	Deviations from linearity in statistical evaluation of linearity in assay validation. Journal of Chemometrics, 2009, 23, 487-494.	0.7	6
82	Statistical Methods for Assessment of Biosimilarity Using Biomarker Data. Journal of Biopharmaceutical Statistics, 2009, 20, 90-105.	0.4	6
83	Nonparametric Tests for Evaluation of Biosimilarity in Variability of Follow-on Biologics. Journal of Biopharmaceutical Statistics, 2014, 24, 1239-1253.	0.4	6
84	Assessing bioequivalence and drug interchangeability. Journal of Biopharmaceutical Statistics, 2017, 27, 272-281.	0.4	6
85	Statistical considerations for rare diseases drug development. Journal of Biopharmaceutical Statistics, 2019, 29, 874-886.	0.4	6
86	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
87	A Two-Stage Design for Drug Screening Trials Based on Continuous Endpoints. Drug Information Journal, 2008, 42, 253-262.	0.5	5
88	A Note on Special Articles on Adaptive Clinical Trial Designs. Journal of Biopharmaceutical Statistics, 2010, 20, 1088-1089.	0.4	5
89	Statistical Considerations in Biosimilar Assessment Using Biosimilarity Index. Journal of Bioequivalence & Bioavailability, 2013, 05, 209-214.	0.1	5
90	On hybrid parallelâ€“crossover designs for assessing drug interchangeability of biosimilar products. Journal of Biopharmaceutical Statistics, 2017, 27, 265-271.	0.4	5

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91	Sample size requirement in analytical studies for similarity assessment. Journal of Biopharmaceutical Statistics, 2017, 27, 233-238.	0.4	5
92	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
93	Sample size reâ€estimation in clinical trials. Statistics in Medicine, 2021, 40, 6133-6149.	0.8	5
94	Replicated Crossover Designs in Bioavailability and Bioequivalence Trials. Drug Information Journal, 1995, 29, 871-884.	0.5	4
95	A Confidence Region Approach for Assessing Equivalence in Variability of Bioavailability. Biometrical Journal, 1996, 38, 475-487.	0.6	4
96	Statistical Methods in Translational Medicine. Journal of the Formosan Medical Association, 2008, 107, S61-S73.	0.8	4
97	Statistical evaluation of the scaled criterion for drug interchangeability. Journal of Biopharmaceutical Statistics, 2017, 27, 282-292.	0.4	4
98	On evaluation of consistency in multi-regional clinical trials. Journal of Biopharmaceutical Statistics, 2018, 28, 840-856.	0.4	4
99	The use of 95% CI or 90% CI for drug product development â€" a controversial issue?. Journal of Biopharmaceutical Statistics, 2019, 29, 834-844.	0.4	4
100	Probability monitoring procedures for sample size determination. Journal of Biopharmaceutical Statistics, 2019, 29, 887-896.	0.4	4
101	The use of real-world data/evidence in regulatory submissions. Contemporary Clinical Trials, 2021, 109, 106521.	0.8	4
102	Guest editor's note: recent issues in bioequivalence trials. Journal of Biopharmaceutical Statistics, 1997, 7, 1-3.	0.4	3
103	Statistical Validation of Traditional Chinese Diagnostic Procedures. Drug Information Journal, 2009, 43, 83-95.	0.5	3
104	Simultaneous confidence interval methods for analytical similarity assessment. Journal of Biopharmaceutical Statistics, 2019, 29, 920-940.	0.4	3
105	Guest Editor's Note: Bioavailability and Bioequivalence. Drug Information Journal, 1995, 29, 793-794.	0.5	2
106	Statistical Test for Ordered Categorical Data in Clinical Trials. Drug Information Journal, 2008, 42, 617-624.	0.5	2
107	Some Controversial Issues in Clinical Trials. Drug Information Journal, 2011, 45, 163-174.	0.5	2
108	On sample size estimation and re-estimation adjusting for variability in confirmatory trials. Journal of Biopharmaceutical Statistics, 2016, 26, 44-54.	0.4	2

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109	On assessing bioequivalence and interchangeability between generics based on indirect comparisons. Statistics in Medicine, 2017, 36, 2978-2993.	0.8	2
110	Analytical similarity assessment. Wiley Interdisciplinary Reviews: Computational Statistics, 2017, 9, e1407.	2.1	2
111	Criteria for dose-finding in two-stage seamless adaptive design. Journal of Biopharmaceutical Statistics, 2019, 29, 908-919.	0.4	2
112	Statistical Evaluation of Clinical Trials Under COVID-19 Pandemic. Therapeutic Innovation and Regulatory Science, 2020, 54, 1551-1556.	0.8	2
113	Some thoughts on the QR method for analytical similarity evaluation. Journal of Biopharmaceutical Statistics, 2020, 30, 521-536.	0.4	2
114	Current Issues in Analytical Similarity Assessment. Statistics in Biopharmaceutical Research, 2021, 13, 203-209.	0.6	2
115	Review of current controversial issues in clinical trials. Annals of General Psychiatry, 2021, 34, e100540.	1.1	2
116	Statistical Tests for One-way/Two-way Translation in Translational Medicine. Journal of the Formosan Medical Association, 2008, 107, S43-S51.	0.8	1
117	Imputation Method Adjusted for Covariates for Nonrespondents in Instruments with Applications. Journal of Biopharmaceutical Statistics, 2011, 21, 342-354.	0.4	1
118	Sample Size and Data Monitoring for Clinical Trials With Extremely Low Incidence Rates. Therapeutic Innovation and Regulatory Science, 2013, 47, 438-446.	0.8	1
119	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
120	Overview of Adaptive Design Methods in Clinical Trials. , 2010, , 1-1-1-19.		1
121	Guest Editorâ€™s Note: Practical and Regulatory Issues on New Drug, New Dosage Form, and Generic Drug Development. Drug Information Journal, 1997, 31, 1145-1147.	0.5	0
122	Editor's Noteâ€”JBS Is now an SCI Journal. Journal of Biopharmaceutical Statistics, 2006, 16, 273-274.	0.4	0
123	Authors' Response to â€œComment on: Cheng, Chow, Burt, and Cosmatos (2008). Statistical Assessment of QT/QTc Prolongation Based on Maximum of Correlated Normal Random Variablesâ€. Journal of Biopharmaceutical Statistics, 2010, 20, 1074-1074.	0.4	0
124	Authors' reply to the letter to the editor by L. Chen and Y. X. Liu. Pharmaceutical Statistics, 2012, 11, 343-345.	0.7	0
125	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
126	On sample size requirement for analytical similarity assessment. Journal of Biopharmaceutical Statistics, 2018, 28, 1143-1159.	0.4	0

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127	Design and Analysis of Biosimilar Studies. ICSA Book Series in Statistics, 2018, , 277-305.	0.0	0
128	Analysis of Two-Stage Adaptive Trial Designs. ICSA Book Series in Statistics, 2018, , 217-241.	0.0	0
129	Practical Issues in Clinical Inspection Process. Therapeutic Innovation and Regulatory Science, 2019, 53, 374-380.	0.8	0
130	Design and Analysis of Biosimilar Switching Studies. Pharmaceutical Medicine, 2019, 33, 379-388.	1.0	0
131	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
132	Innovative Thinking on Endpoint Selection in Clinical Trials. Journal of Biopharmaceutical Statistics, 2019, 29, 941-951.	0.4	0
133	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
134	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
135	Test for Ordered Categorical Data. , 2010, , 1338-1342.		0
136	Clinical Strategy for Study Endpoint Selection. , 2010, , 19-1-19-15.		0
137	Innovative Design and Analysis for PK/PD Biosimilar Bridging Studies with Multiple References. AAPS Journal, 2022, 24, 3.	2.2	0