

# M Sam Salek

## List of Publications by Year in descending order

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Version: 2024-02-01

118  
papers

4,985  
citations

159585

30  
h-index

102487

66  
g-index

122  
all docs

122  
docs citations

122  
times ranked

4571  
citing authors

#	ARTICLE	IF	CITATIONS
1	Comparison of the registration process of the medicines control authority of Zimbabwe with Australia, Canada, Singapore, and Switzerland: benchmarking best practices. <i>Expert Review of Clinical Pharmacology</i> , 2022, 15, 109-119.	3.1	4
2	Quality of life assessment in core outcome sets: A position statement of the EADV Task Force on Quality of Life and Patient Oriented Outcomes. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2022, 36, 20-23.	2.4	9
3	Biosimilar development and review process in the BRICS-TM countries: Proposal for a standardized model to improve regulatory performance. <i>Expert Review of Clinical Pharmacology</i> , 2022, , 1-22.	3.1	1
4	The validity, responsiveness, and score interpretation of the PROMIS <sup>®</sup> Physical Function â€œ Multiple Sclerosis 15a short form in multiple sclerosis. <i>Multiple Sclerosis and Related Disorders</i> , 2022, 62, 103753.	2.0	2
5	Pharmaceutical Industry Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. <i>Frontiers in Medicine</i> , 2022, 9, 898725.	2.6	6
6	Regulatory Authority Evaluation of the Effectiveness and Efficiency of the ZaZiBoNa Collaborative Medicines Registration Initiative: The Way Forward. <i>Frontiers in Medicine</i> , 2022, 9, 898743.	2.6	9
7	A comparison of the measurement properties of the PROMIS-Fatigue (MS) 8a against legacy fatigue questionnaires. <i>Multiple Sclerosis and Related Disorders</i> , 2022, , 104048.	2.0	6
8	Methods to improve quality of life, beyond medicines. Position statement of the European Academy of Dermatology and Venereology Task Force on Quality of Life and Patient Oriented Outcomes. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2021, 35, 318-328.	2.4	22
9	Evaluation of the Regulatory Review Process in Zimbabwe: Challenges and Opportunities. <i>Therapeutic Innovation and Regulatory Science</i> , 2021, 55, 474-489.	1.6	12
10	Validation of the German version of the Family Reported Outcome Measure (FROM-16) to assess the impact of disease on the partner or family member. <i>Health and Quality of Life Outcomes</i> , 2021, 19, 106.	2.4	6
11	Measuring the impact of COVID-19 on the quality of life of the survivors, partners and family members: a cross-sectional international online survey. <i>BMJ Open</i> , 2021, 11, e047680.	1.9	68
12	Patient-reported outcomes in clinical trials for multiple myeloma: Where we are.. <i>Journal of Clinical Oncology</i> , 2021, 39, e18615-e18615.	1.6	2
13	Quality of life measurement in alopecia areata. Position statement of the European Academy of Dermatology and Venereology Task Force on Quality of Life and Patient Oriented Outcomes. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2021, 35, 1614-1621.	2.4	18
14	Clinical experience and psychometric properties of the Cardiff Acne Disability Index (CADI)*. <i>British Journal of Dermatology</i> , 2021, 185, 711-724.	1.5	12
15	South African Regulatory Authority: The Impact of Reliance on the Review Process Leading to Improved Patient Access. <i>Frontiers in Pharmacology</i> , 2021, 12, 699063.	3.5	12
16	Challenges Faced by the Biopharmaceutical Industry in the Development and Marketing Authorization of Biosimilar Medicines in BRICS-TM Countries: An Exploratory Study. <i>Pharmaceutical Medicine</i> , 2021, 35, 235-251.	1.9	8
17	Evaluation of the Review Models and Approval Timelines of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward. <i>Frontiers in Medicine</i> , 2021, 8, 742200.	2.6	7
18	Comparison of BRICS-TM Countries' Biosimilar Regulatory Frameworks With Australia, Canada and Switzerland: Benchmarking Best Practices. <i>Frontiers in Pharmacology</i> , 2021, 12, 711361.	3.5	3

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19	Evaluation of the Good Review Practices of Countries Participating in the Southern African Development Community: Alignment and Strategies for Moving Forward. <i>Frontiers in Medicine</i> , 2021, 8, 742181.	2.6	5
20	Family reported outcomes, an unmet need in the management of a patient's disease: appraisal of the literature. <i>Health and Quality of Life Outcomes</i> , 2021, 19, 194.	2.4	15
21	Standardizing fatigue measurement in multiple sclerosis: the validity, responsiveness and score interpretation of the PROMIS SF v1.0 " Fatigue (MS) 8a. <i>Multiple Sclerosis and Related Disorders</i> , 2021, 54, 103117.	2.0	10
22	Current Regulatory Requirements for Biosimilars in Six Member Countries of BRICS-TM: Challenges and Opportunities. <i>Frontiers in Medicine</i> , 2021, 8, 726660.	2.6	6
23	Itch and Mental Health in Dermatological Patients across Europe: A Cross-Sectional Study in 13 Countries. <i>Journal of Investigative Dermatology</i> , 2020, 140, 568-573.	0.7	44
24	Development of the pyruvate kinase deficiency diary and pyruvate kinase deficiency impact assessment: Disease-specific assessments. <i>European Journal of Haematology</i> , 2020, 104, 427-434.	2.2	9
25	Quality of life measurement in occupational skin diseases. Position paper of the European Academy of Dermatology and Venereology Task Forces on Quality of Life and Patient Oriented Outcomes and Occupational Skin Disease. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2020, 34, 1924-1931.	2.4	17
26	Implementation of a Framework for an Abridged Review Using Good Reliance Practices: Optimising the Medicine Regulatory Review Process in South Africa. <i>Therapeutic Innovation and Regulatory Science</i> , 2020, 54, 1199-1207.	1.6	7
27	Evaluating the Success of ZaZiBoNa, the Southern African Development Community Collaborative Medicines Registration Initiative. <i>Therapeutic Innovation and Regulatory Science</i> , 2020, 54, 1319-1329.	1.6	25
28	Quality-of-life issues and symptoms reported by patients living with haematological malignancy: a qualitative study. <i>Therapeutic Advances in Hematology</i> , 2020, 11, 204062072095500.	2.5	12
29	Reliability of a Novel Hematological Malignancy Specific Patient-Reported Outcome Measure: HM-PRO. <i>Frontiers in Pharmacology</i> , 2020, 11, 571066.	3.5	3
30	Position statement of the European Academy of Dermatology and Venereology Task Force on Quality of Life and Patient Oriented Outcomes on quality of life issues in dermatologic patients during the COVID-19 pandemic. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2020, 34, 1666-1671.	2.4	30
31	Can Standardisation of the Public Assessment Report Improve Benefit-Risk Communication?. <i>Frontiers in Pharmacology</i> , 2020, 11, 855.	3.5	6
32	Development of a Novel Hematological Malignancy Specific Patient-Reported Outcome Measure (HM-PRO): Content Validity. <i>Frontiers in Pharmacology</i> , 2020, 11, 209.	3.5	9
33	Evaluation of the Performance of the South Africa Regulatory Agency: Recommendations for Improved Patients' Access to Medicines. <i>Therapeutic Innovation and Regulatory Science</i> , 2020, 54, 878-887.	1.6	8
34	Quality Decision Making in Health Technology Assessment: Issues Facing Companies and Agencies. <i>Therapeutic Innovation and Regulatory Science</i> , 2020, 54, 275-282.	1.6	2
35	Patients' Perspectives of the Pharmaceutical Regulatory and Reimbursement Systems in Istanbul, Turkey. <i>Therapeutic Innovation and Regulatory Science</i> , 2020, 54, 1086-1096.	1.6	1
36	A Proposed Regulatory Review Model to Support the South African Health Products Regulatory Authority to Become a More Efficient and Effective Agency. <i>International Journal of Health Policy and Management</i> , 2020, , .	0.9	3

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37	Hematological Malignancy Specific Patient-Reported Outcome Measure (HM-PRO): Construct Validity Study. <i>Frontiers in Pharmacology</i> , 2020, 11, 1308.	3.5	7
38	Haematological malignancy: Are we measuring what is important to patients? A systematic review of quality of life instruments. <i>European Journal of Haematology</i> , 2019, 102, 279-311.	2.2	18
39	Factors Influencing Delays in Patient Access to New Medicines in Canada: A Retrospective Study of Reimbursement Processes in Public Drug Plans. <i>Frontiers in Pharmacology</i> , 2019, 10, 196.	3.5	17
40	The South African Medicines Control Council: Comparison of Its Registration Process With Australia, Canada, Singapore, and Switzerland. <i>Frontiers in Pharmacology</i> , 2019, 10, 228.	3.5	9
41	Validation of the electronic Psoriasis Area and Severity Index application: Establishing measurement equivalence. <i>Journal of the American Academy of Dermatology</i> , 2019, 81, 1439-1441.	1.2	4
42	Paper and electronic versions of HM-PRO, a novel patient-reported outcome measure for hematology: an equivalence study. <i>Journal of Comparative Effectiveness Research</i> , 2019, 8, 523-533.	1.4	12
43	Quality Decision Making in Health Technology Assessment: Issues Facing Companies and Agencies. <i>Therapeutic Innovation and Regulatory Science</i> , 2019, , 216847901983366.	1.6	2
44	The Reliability and Relevance of a Quality of Decision Making Instrument, Quality of Decision-Making Orientation Scheme (QoDoS), for Use During the Lifecycle of Medicines. <i>Frontiers in Pharmacology</i> , 2019, 10, 17.	3.5	6
45	Validation of the Thai version of the family reported outcome measure (FROM-16) to assess the impact of disease on the partner or family members of patients with cancer. <i>Health and Quality of Life Outcomes</i> , 2019, 17, 32.	2.4	11
46	Presenting signs and patient co-variables in Gaucher disease: outcome of the Gaucher Earlier Diagnosis Consensus (GED) Delphi initiative. <i>Internal Medicine Journal</i> , 2019, 49, 578-591.	0.8	39
47	Appraisal of patient-reported outcome measures in analogous diseases and recommendations for use in phase II and III clinical trials of pyruvate kinase deficiency. <i>Quality of Life Research</i> , 2019, 28, 399-410.	3.1	9
48	Occurrence, Chronicity and Intensity of Itch in a Clinical Consecutive Sample of Patients with Skin Diseases: A Multi-centre Study in 13 European Countries. <i>Acta Dermato-Venereologica</i> , 2019, 99, 146-151.	1.3	27
49	Quality of life measurement in acne. Position Paper of the European Academy of Dermatology and Venereology Task Forces on Quality of Life and Patient Oriented Outcomes and Acne, Rosacea and Hidradenitis Suppurativa. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2018, 32, 194-208.	2.4	51
50	Quimp (quality of life impairment): an addition to the quality of life lexicon. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2018, 32, e181-e182.	2.4	28
51	Conceptualization, development and validation of QoL <sup>©</sup> (Teenagers <sup>™</sup> Quality of Life): a patient-focused measure to assess quality of life of adolescents with skin diseases. <i>British Journal of Dermatology</i> , 2018, 178, 161-175.	1.5	22
52	The South African Regulatory System: Past, Present, and Future. <i>Frontiers in Pharmacology</i> , 2018, 9, 1407.	3.5	11
53	Correlating the Dermatology Life Quality Index with psychiatric measures: A systematic review. <i>Clinics in Dermatology</i> , 2018, 36, 691-697.	1.6	9
54	Quality, Non-clinical and Clinical Considerations for Biosimilar Monoclonal Antibody Development: EU, WHO, USA, Canada, and BRICS-TM Regulatory Guidelines. <i>Frontiers in Pharmacology</i> , 2018, 9, 1079.	3.5	17

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55	The burden of disease in pyruvate kinase deficiency: Patients'™ perception of the impact on health-related quality of life. <i>European Journal of Haematology</i> , 2018, 101, 758-765.	2.2	25
56	The Regulatory Review Process in South Africa: Challenges and Opportunities for a New Improved System. <i>Therapeutic Innovation and Regulatory Science</i> , 2018, 52, 449-458.	1.6	18
57	Approaches to the Development and Use of PRO Measures: A New Roadmap. , 2018, , 15-49.		0
58	A systematic review of the use of quality-of-life instruments in randomized controlled trials for psoriasis. <i>British Journal of Dermatology</i> , 2017, 176, 577-593.	1.5	53
59	Health Technology Assessment (HTA) Case Studies: Factors Influencing Divergent HTA Reimbursement Recommendations in Australia, Canada, England, and Scotland. <i>Value in Health</i> , 2017, 20, 320-328.	0.3	53
60	Comparison of the paper-based and electronic versions of the Dermatology Life Quality Index: evidence of equivalence. <i>British Journal of Dermatology</i> , 2017, 177, 1306-1315.	1.5	27
61	Emerging Guidelines for Patient Engagement in Research. <i>Value in Health</i> , 2017, 20, 481-486.	0.3	144
62	Mapping of the DLQI scores to EQ-5D utility values using ordinal logistic regression. <i>Quality of Life Research</i> , 2017, 26, 3025-3034.	3.1	23
63	Assessing the Quality of Decision Making in the Development and Regulatory Review of Medicines: Identifying Biases and Best Practices. <i>Therapeutic Innovation and Regulatory Science</i> , 2017, 51, 250-256.	1.6	9
64	The burden of common skin diseases assessed with the EQ5D,¢: a European multicentre study in 13 countries. <i>British Journal of Dermatology</i> , 2017, 176, 1170-1178.	1.5	106
65	Quality of life improvement in older patients with heart failure initiated on ivabradine: Results from the UK multi-centre LIVE:LIFE prospective cohort study. <i>International Journal of Cardiology</i> , 2017, 249, 313-318.	1.7	19
66	Establishing the values for patient engagement (PE) in health-related quality of life (HRQoL) research: an international, multiple-stakeholder perspective. <i>Quality of Life Research</i> , 2017, 26, 1393-1404.	3.1	27
67	Why quality of life measurement is important in dermatology clinical practice. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2017, 31, 424-431.	2.4	69
68	Quality of life measurement in atopic dermatitis. Position paper of the European Academy of Dermatology and Venereology (<scp>EADV</scp>) Task Force on quality of life. <i>Journal of the European Academy of Dermatology and Venereology</i> , 2017, 31, 576-593.	2.4	53
69	A Comparison of Reimbursement Recommendations by European HTA Agencies: Is There Opportunity for Further Alignment?. <i>Frontiers in Pharmacology</i> , 2017, 8, 384.	3.5	61
70	Evaluating Quality of Decision-Making Processes in Medicines' Development, Regulatory Review, and Health Technology Assessment: A Systematic Review of the Literature. <i>Frontiers in Pharmacology</i> , 2017, 8, 189.	3.5	19
71	Evaluating alignment between Canadian Common Drug Review reimbursement recommendations and provincial drug plan listing decisions: an exploratory study. <i>CMAJ Open</i> , 2016, 4, E674-E678.	2.4	18
72	The Development and Validation of a Generic Instrument, QoDoS, for Assessing the Quality of Decision Making. <i>Frontiers in Pharmacology</i> , 2016, 7, 180.	3.5	13

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73	Patient-centered research and practice in the era of genomics: a novel approach. <i>Haematologica</i> , 2016, 101, 792-793.	3.5	1
74	Using PROMs in Healthcare: Who Should Be in the Driving Seat? Policy Makers, Health Professionals, Methodologists or Patients?. <i>Patient</i> , 2016, 9, 495-498.	2.7	19
75	Interpretation of Renal Quality of Life Profile scores in routine clinical practice: an aid to treatment decision-making. <i>Quality of Life Research</i> , 2016, 25, 1697-1702.	3.1	5
76	Quality of Regulatory Decision-Making Practices: Issues Facing Companies and Agencies. <i>Therapeutic Innovation and Regulatory Science</i> , 2016, 50, 487-495.	1.6	10
77	Key Presenting Signs and Patient Co-Variables in Early Diagnosis of Type 3 Gaucher Disease: A Global Delphi Consensus Initiative. <i>Blood</i> , 2016, 128, 4886-4886.	1.4	1
78	Development of a Novel Patient-Reported Outcome Measure in Haematological Malignancy for Use in Routine Clinical Practice: Item Generation. <i>Blood</i> , 2016, 128, 5985-5985.	1.4	6
79	A Global Delphi Consensus Initiative for Early Diagnosis of Gaucher Disease: Key Presenting Signs and Patient Co-Variables in Type 1 Disease. <i>Blood</i> , 2016, 128, 3676-3676.	1.4	0
80	A Global Delphi Consensus Initiative for Early Diagnosis of Gaucher Disease: Barriers, Their Resolution and the Impact on Patients. <i>Blood</i> , 2016, 128, 4885-4885.	1.4	0
81	Appropriate and inappropriate influences on outpatient discharge decision making in dermatology: a prospective qualitative study. <i>British Journal of Dermatology</i> , 2015, 173, 720-730.	1.5	7
82	A practical approach to communicating benefit-risk decisions of medicines to stakeholders. <i>Frontiers in Pharmacology</i> , 2015, 6, 99.	3.5	8
83	Patient and public engagement in health-related quality of life and patient-reported outcomes research: what is important and why should we care? Findings from the first ISOQOL patient engagement symposium. <i>Quality of Life Research</i> , 2015, 24, 1069-1076.	3.1	65
84	PFI-14: A Rasch Analysis Refinement of the Psoriasis Family Index. <i>Dermatology</i> , 2015, 231, 15-23.	2.1	13
85	Factors influencing quality decision-making: regulatory and pharmaceutical industry perspectives. <i>Pharmacoepidemiology and Drug Safety</i> , 2015, 24, 319-328.	1.9	25
86	The Psychological Burden of Skin Diseases: A Cross-Sectional Multicenter Study among Dermatological Out-Patients in 13 European Countries. <i>Journal of Investigative Dermatology</i> , 2015, 135, 984-991.	0.7	619
87	Determining the Minimal Clinically Important Difference and Responsiveness of the Dermatology Life Quality Index (DLQI): Further Data. <i>Dermatology</i> , 2015, 230, 27-33.	2.1	293
88	An Evaluation of the Efficiency of the Gulf Cooperation Council's Centralized Procedure by the Gulf Regulatory Authorities and Pharmaceutical Companies: Recommendations for an Improved Model. <i>Therapeutic Innovation and Regulatory Science</i> , 2015, 49, 560-568.	1.6	2
89	Equivalence of electronic and paper-based patient-reported outcome measures. <i>Quality of Life Research</i> , 2015, 24, 1949-1961.	3.1	112
90	Streamlining the Validation of Patient Reported Outcome (PRO) Measures in Drug Regulatory Processes. <i>Pharmaceutical Medicine</i> , 2015, 29, 255-268.	1.9	0

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91	A Universal Framework for the Benefit-Risk Assessment of Medicines: Is This the Way Forward?. Therapeutic Innovation and Regulatory Science, 2015, 49, 17-25.	1.6	25
92	Strategy for communicating benefit-risk decisions: a comparison of regulatory agencies' publicly available documents. Frontiers in Pharmacology, 2014, 5, 269.	3.5	6
93	The development and validation of the Family Reported Outcome Measure (FROM-16)® to assess the impact of disease on the partner or family member. Quality of Life Research, 2014, 23, 317-326.	3.1	31
94	Evaluation of the Gulf Cooperation Council Centralized Procedure: The Way Forward. Therapeutic Innovation and Regulatory Science, 2014, 48, 709-716.	1.6	4
95	Clinical experience and psychometric properties of the Children's Dermatology Life Quality Index (CDLQI), 1995-2012. British Journal of Dermatology, 2013, 169, 734-759.	1.5	80
96	Is there a need for a universal benefit-risk assessment framework for medicines? Regulatory and industry perspectives. Pharmacoepidemiology and Drug Safety, 2013, 22, 1004-1012.	1.9	22
97	Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy, 2013, 113, 305-312.	3.0	31
98	The impact of disease on family members: a critical aspect of medical care. Journal of the Royal Society of Medicine, 2013, 106, 399-407.	2.0	112
99	The Dermatitis Family Impact questionnaire: a review of its measurement properties and clinical application. British Journal of Dermatology, 2013, 169, 31-46.	1.5	37
100	The impact of patients' chronic disease on family quality of life: an experience from 26 specialties. International Journal of General Medicine, 2013, 6, 787.	1.8	115
101	Quality of life measurement in dermatology consultation: impact on patient reported outcomes. Giornale Italiano Di Dermatologia E Venereologia, 2013, 148, 263-75.	0.8	2
102	Development and Application of Scorecards to Assess the Quality of a Regulatory Submission and Its Review. Drug Information Journal, 2012, 46, 73-83.	0.5	4
103	Dermatology Life Quality Index (DLQI): A Paradigm Shift to Patient-Centered Outcomes. Journal of Investigative Dermatology, 2012, 132, 2464-2465.	0.7	35
104	The Role of the EQ-5D in the Economic Evaluation of Dermatological Conditions and Therapies. Dermatology, 2012, 225, 45-53.	2.1	23
105	An Appraisal of Good Regulatory Review Practices in the Gulf Cooperation Council States. Drug Information Journal, 2012, 46, 57-64.	0.5	7
106	Regulatory Review Process in the Gulf Cooperation Council States: Similarities and Differences. Drug Information Journal, 2012, 46, 65-72.	0.5	2
107	Adolescents with Skin Disease Have Specific Quality of Life Issues. Dermatology, 2009, 218, 357-366.	2.1	41
108	Measurement of family impact of skin disease: further validation of the Family Dermatology Life Quality Index (FDLQI). Journal of the European Academy of Dermatology and Venereology, 2008, 22, 813-821.	2.4	49

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109	The Dermatology Life Quality Index 1994-2007: a comprehensive review of validation data and clinical results. <i>British Journal of Dermatology</i> , 2008, 159, 997-1035.	1.5	544
110	The Practical Reality of Using a Patient-Reported Outcome Measure in a Routine Dermatology Clinic. <i>Dermatology</i> , 2007, 215, 315-319.	2.1	32
111	Does enough quality of life-related discussion occur during dermatology outpatient consultations?. <i>British Journal of Dermatology</i> , 2005, 153, 997-1000.	1.5	33
112	Translating the Science of Quality of Life into Practice: What Do Dermatology Life Quality Index Scores Mean?. <i>Journal of Investigative Dermatology</i> , 2005, 125, 659-664.	0.7	614
113	Development of external methods to evaluate the quality of pharmacy services offered by community pharmacists. <i>Quality Assurance Journal</i> , 2003, 7, 248-257.	0.1	3
114	Intramuscular Alefacept Improves Health-Related Quality of Life in Patients with Chronic Plaque Psoriasis. <i>Dermatology</i> , 2003, 206, 307-315.	2.1	91
115	An international postgraduate course in pharmaceutical medicine: a 25-year review. <i>Pharmaceutical Medicine</i> , 2001, 15, 261-263.	0.4	6
116	Questionnaire techniques in assessing acne handicap: Reliability and validity study. <i>Quality of Life Research</i> , 1996, 5, 131-138.	3.1	64
117	Validation of Sickness Impact Profile and Psoriasis Disability Index in psoriasis. <i>British Journal of Dermatology</i> , 1990, 123, 751-756.	1.5	306
118	Evaluation of the Effectiveness and Efficiency of the East African Community Joint Assessment Procedure by Member Countries: The Way Forward. <i>Frontiers in Pharmacology</i> , 0, 13, .	3.5	5