

Kengo Nagashima

PROJECT ASSOCIATE PROFESSOR · BIOSTATISTICIAN

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Research Interests

Biostatistics & Statistical Methodology: My (current) primary research interests are (1) Survival Analysis and Model Selection, (2) Meta-analysis and Inference for Random-effects Models, and (3) Model Misspecification. I am also interested in Biomarkers in Clinical Trials, Missing Data, Causal Inference, Semiparametric Models, Estimating Equations, Bayesian Inference, Inference for High-dimensional Data, Statistical Machine Learning, Genetic Epidemiology, Population Pharmacokinetics, Cancer Clinical Trials, Quasi-likelihood Method, and Quasi-Monte Carlo Integration.

Professional Positions

Keio University School of Medicine

VISITING ASSOCIATE PROFESSOR

Tokyo, Japan

November 2018–present

Research Center for Medical and Health Data Science, The Institute of Statistical Mathematics

PROJECT ASSOCIATE PROFESSOR

Tokyo, Japan

April 2018–present

Graduate School of Engineering, Tokyo University of Science

LECTURER (PART-TIME)

Tokyo, Japan

April 2016–present

Department of Global Clinical Research, Graduate School of Medicine, Chiba University

RESEARCH ASSISTANT PROFESSOR

Chiba, Japan

April 2015–March 2018

Clinical Research Center, Chiba University Hospital

RESEARCH ASSISTANT PROFESSOR

Chiba, Japan

April 2013–March 2015

Faculty of Pharmaceutical Sciences, Josai University

RESEARCH ASSOCIATE

Saitama, Japan

April 2008–March 2013

Education

Tokyo University of Science

PH.D. IN ENGINEERING

Tokyo, Japan

April 2010–March 2014

Dissertation: “Statistical screening methods for pharmacokinetics-related genes in genome-wide studies”

Tokyo University of Science

M.SC. IN ENGINEERING

Tokyo, Japan

April 2006–March 2008

Master's Thesis: “A comparison of statistical methods for SNP association analysis under Hardy–Weinberg disequilibrium”

Tokyo University of Science

B.SC. IN ENGINEERING

Tokyo, Japan

April 2002–March 2006

Publications (Peer-Reviewed)

STATISTICAL METHODOLOGY

- 1 Nagashima K, Noma H, Furukawa TA. Prediction intervals for random-effects meta-analysis: a confidence distribution approach. *Statistical Methods in Medical Research* 2018. *In press*. DOI: [10.1177/0962280218773520](https://doi.org/10.1177/0962280218773520). [[arXiv:1804.01054](https://arxiv.org/abs/1804.01054)] [[Postprint](#)].
- 2 Noma H, Nagashima K, Maruo K, Gosho M, Furukawa TA. Bartlett-type corrections and bootstrap adjustments of likelihood-based inference methods for network meta-analysis. *Statistics in Medicine* 2018; **37**(7): 1178–1190. DOI: [10.1002/sim.7578](https://doi.org/10.1002/sim.7578).
- 3 Nagashima K, Sato Y. Information criteria for Firth's penalized partial likelihood approach in Cox regression models. *Statistics in Medicine* 2017; **36**(21): 3422–3436. DOI: [10.1002/sim.7368](https://doi.org/10.1002/sim.7368). [[Postprint](#)].
- 4 Noma H, Nagashima K. A note on the Mantel–Haenszel estimators when the common effect assumptions are violated. *Epidemiologic Methods* 2016; **5**(1): 19–35. DOI: [10.1515/em-2015-0004](https://doi.org/10.1515/em-2015-0004).
- 5 Nagashima K, Sato Y, Noma H, Hamada C. An efficient and robust method for analyzing population pharmacokinetic data in genome-wide pharmacogenomic studies: a generalized estimating equation approach. *Statistics in Medicine* 2013; **32**(27): 4838–4858. DOI: [10.1002/sim.5895](https://doi.org/10.1002/sim.5895). [[arXiv:1805.05017](https://arxiv.org/abs/1805.05017)]
- 6 Gosho M, Nagashima K, Sato Y. Study designs and statistical analyses for biomarker research. *Sensors* 2012; **12**(7): 8966–8986. DOI: [10.3390/s120708966](https://doi.org/10.3390/s120708966). (Review)
- 7 Nagashima K, Sato Y, Hamada C. A modified maximum contrast method for unequal sample sizes in pharmacogenomic studies. *Statistical Applications in Genetics and Molecular Biology* 2011; **10**(1): Article 41. DOI: [10.2202/1544-6115.1560](https://doi.org/10.2202/1544-6115.1560).
- 8 Sato Y, Laird NM, Nagashima K, Kato R, Hamano T, Yafune A, Kaniwa N, Saito Y, Sugiyama E, Kim S-R, Furuse J, Ishii H, Ueno H, Okusaka T, Saijo N, Sawada J-i, Yoshida T. A new statistical screening approach for finding pharmacokinetics-related genes in genome-wide studies. *The Pharmacogenomics Journal* 2009; **9**(2): 137–146. DOI: [10.1038/tpj.2008.17](https://doi.org/10.1038/tpj.2008.17).

APPLICATIONS IN BIostatISTICS

- 9 Gosho M, Sato Y, Nagashima K, Takahashi S. Trends in study design and the statistical methods employed in a leading general medicine journal. *Journal of Clinical Pharmacy and Therapeutics* 2018; **43**(1): 36–44. DOI: [10.1111/jcpt.12605](https://doi.org/10.1111/jcpt.12605).
- 10 Sato Y, Gosho M, Nagashima K, Takahashi S, Ware JH, Laird NM. Statistical methods in the *Journal* — an update. *New England Journal of Medicine* 2017; **376**(11):1086–1087. DOI: [10.1056/NEJMc1616211](https://doi.org/10.1056/NEJMc1616211). (Correspondence)

MEDICAL RESEARCHES

- 11 Matsumura T, Terada J, Yoshimura C, Koshikawa K, Kinoshita T, Yahaba M, Nagashima K, Sakao S, Tatsumi K. Single-use suvorexant for treating insomnia during overnight polysomnography in patients with suspected obstructive sleep apnea: a single-center experience. *Drug Design, Development and Therapy* 2019. *In press*.
- 12 Hashimoto J, Kato K, Ito Y, Kojima T, Akimoto T, Daiko H, Hamamoto Y, Matsushita H, Katano S, Hara H, Tanaka Y, Saito Y, Nagashima K, Igaki H. Phase II feasibility study of preoperative concurrent chemoradiotherapy with cisplatin plus 5-fluorouracil and elective lymph node irradiation for clinical stage II/III esophageal squamous cell carcinoma. *International Journal of Clinical Oncology* 2019; **24**(1): 70–74. DOI: [10.1007/s10147-018-1336-x](https://doi.org/10.1007/s10147-018-1336-x).
- 13 Hiramoto S, Tamaki T, Nagashima K, Hori T, Kikuchi A, Yoshioka A, Inoue A. Prognostic factors in patients who received end-of-life chemotherapy for advanced cancer. *International Journal of Clinical Oncology* 2018. *In press*. DOI: [10.1007/s10147-018-1363-7](https://doi.org/10.1007/s10147-018-1363-7).

- Honma Y, Terauchi T, Tateishi U, Kano D, Nagashima K, Iwasa S, Takashima A, Kato K, Hamaguchi T, Boku N, Shimada Y,
14 Yamada Y. Imaging peritoneal metastasis of gastric cancer with ¹⁸F-fluorothymidine positron emission tomography/computed tomography: a proof-of-concept study. *British Journal of Radiology* 2018; **91**(1089): 20180259. DOI: [10.1259/bjr.20180259](https://doi.org/10.1259/bjr.20180259).
- Fujita M, Sato Y, Nagashima K, Takahashi S, Hata A. Medical costs attributable to overweight and obesity in Japanese
15 individuals. *Obesity Research & Clinical Practice* 2018; **12**(5): 479–484. DOI: [10.1016/j.orcp.2018.06.002](https://doi.org/10.1016/j.orcp.2018.06.002).
- Nishi T, Kitahara H, Fujimoto Y, Nakayama T, Nagashima K, Hanaoka H, Kobayashi Y. Intravenous nicorandil versus adenosine
16 for fractional flow reserve measurement: A crossover, randomized study. *Heart and Vessels* 2018; **33**(12): 1570–1575. DOI: [10.1007/s00380-018-1197-2](https://doi.org/10.1007/s00380-018-1197-2).
- Misawa S, Kuwabara S, Sato Y, Yamaguchi N, Nagashima K, Katayama K, Sekiguchi Y, Iwai Y, Amino H, Suichi T, Yokota T, Nishida
17 Y, Kanouchi T, Kohara N, Kawamoto M, Ishii J, Kuwahara M, Suzuki H, Hirata K, Kokubun N, Masuda R, Kaneko J, Yabe I, Sasaki
H, Kaida K-i, Takazaki H, Suzuki N, Suzuki S, Nodera H, Matsui N, Tsuji S, Koike H, Yamasaki R, Kusunoki S, for the Japanese
Eculizumab Trial for GBS (JET-GBS) Study Group. Safety and efficacy of eculizumab in Guillain–Barré syndrome: a multicentre,
double-blind, randomised phase 2 trial. *The Lancet Neurology* 2018; **17**(6): 519–529. DOI: [10.1016/S1474-4422\(18\)30114-5](https://doi.org/10.1016/S1474-4422(18)30114-5).
- Fujita M, Sugiyama M, Sato Y, Nagashima K, Takahashi S, Mizogami M, Hata A. Hepatitis B virus reactivation in patients with
18 rheumatoid arthritis: Analysis of the National Database of Japan. *Journal of Viral Hepatitis* 2018; **25**(11): 1312–1320. DOI: [10.1111/jvh.12933](https://doi.org/10.1111/jvh.12933).
- Matsumura T, Terada J, Kinoshita T, Sakurai Y, Yahaba M, Tsushima K, Sakao S, Nagashima K, Ozaki T, Kobayashi Y, Hiwasa T,
19 Tatsumi K. Circulating autoantibodies against neuroblastoma suppressor of tumorigenicity 1 (NBL1): a potential biomarker for
coronary artery disease in patients with obstructive sleep apnea. *PLoS ONE* 2018; **13**(3): e0195015. DOI: [10.1371/journal.pone.0195015](https://doi.org/10.1371/journal.pone.0195015).
- Yamaguchi T, Kato K, Nagashima K, Iwasa S, Honma Y, Takashima A, Hamaguchi T, Ito Y, Itami J, Boku N, Higuchi K. Type of
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esophageal squamous cell carcinoma. *International Journal of Clinical Oncology* 2018; **23**(4): 652–658. DOI: [10.1007/s10147-018-1258-7](https://doi.org/10.1007/s10147-018-1258-7).
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cingulate cortex is associated with neuropathic pain. *Journal of Neurology, Neurosurgery, and Psychiatry* 2018; **89**(10):
1082–1087. DOI: [10.1136/jnnp-2017-316601](https://doi.org/10.1136/jnnp-2017-316601).
- Kotooka N, Kitakaze M, Nagashima K, Asaka M, Kinugasa Y, Nochioka K, Mizuno A, Nagatomo D, Mine D, Yamada Y, Kuratomi A,
22 Okada N, Fujimatsu D, Kuwahata S, Toyoda S, Hirotsu S-i, Komori T, Eguchi K, Kario K, Inomata T, Sugi K, Yamamoto K, Tsutsui
H, Masuyama T, Shimokawa H, Momomura S-i, Seino Y, Sato Y, Inoue T, Node K, On behalf of the HOMES-HF study
investigators. The first multicenter, randomized, controlled trial of home telemonitoring for Japanese patients with heart
failure: home telemonitoring study for patients with heart failure (HOMES-HF). *Heart and Vessels* 2018; **33**(8): 866–876. DOI: [10.1007/s00380-018-1133-5](https://doi.org/10.1007/s00380-018-1133-5).
- Inagaki T, Terada J, Yahaba M, Kawata N, Jujo T, Nagashima K, Sakao S, Tanabe N, Tatsumi K. Heart rate and oxygen saturation
23 change patterns during a 6-min walk test in subjects with chronic thromboembolic pulmonary hypertension. *Respiratory Care*
2018; **63**(5): 573–583. DOI: [10.4187/respcare.05788](https://doi.org/10.4187/respcare.05788)
- Sasaki Y, Iwasa S, Okazaki S, Goto M, Kojima Y, Naganuma A, Nagashima K, Nagai Y, Hirano H, Honma Y, Takashima A, Kato K,
24 Hamaguchi T. A phase II study of combination therapy with oral S-1 and cisplatin in elderly patients with advanced gastric
cancer. *Gastric Cancer* 2018; **21**(3): 439–445. DOI: [10.1007/s10120-017-0753-2](https://doi.org/10.1007/s10120-017-0753-2).

- 25 Yanai T, Iwasa S, Hashimoto H, Ohyanagi F, Takiguchi T, Takeda K, Nakao M, Sakai H, Nakayama T, Minato K, Arai T, Suzuki K, Shimada Y, Nagashima K, Terakado H, Yamamoto N. A double-blind randomized phase II dose-finding study of olanzapine 10 mg or 5 mg for the prophylaxis of emesis induced by highly emetogenic cisplatin-based chemotherapy. *International Journal of Clinical Oncology* 2018; **23**(2): 382–388. DOI: [10.1007/s10147-017-1200-4](https://doi.org/10.1007/s10147-017-1200-4)
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- 27 Korematsu S, Nagashima K, Sato Y, Nagao M, Hasegawa S, Nakamura H, Sugiura S, Miura K, Okada K, Fujisawa T. “Spike” in acute asthma exacerbations during enterovirus D68 epidemic in Japan: A nation-wide survey. *Allergology International* 2018; **67**(1): 55–60. DOI: [10.1016/j.alit.2017.04.003](https://doi.org/10.1016/j.alit.2017.04.003).
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- 30 Honma Y, Hokamura N, Nagashima K, Sudo K, Shoji H, Iwasa S, Takashima A, Kato K, Hamaguchi T, Boku N, Ito Y, Itami J, Koyanagi K, Igaki H, Tachimori Y. Clinical outcomes of resectable esophageal cancer with supraclavicular lymph node metastases treated with curative intent. *Anticancer Research* 2017; **37**(7): 3741–3749. DOI: [10.21873/anticancer.11748](https://doi.org/10.21873/anticancer.11748).
- 31 Nishide A, Fujita M, Sato Y, Nagashima K, Takahashi S, Hata A. Income-related inequalities in access to dental care services in Japan. *International Journal of Environmental Research and Public Health* 2017; **14**(5): 524. DOI: [10.3390/ijerph14050524](https://doi.org/10.3390/ijerph14050524).
- 32 Shoji H, Heike Y, Tada K, Kitano S, Nishimura T, Shimada Y, Nagashima K, Aoki K, Hiraoka N, Honma Y, Iwasa S, Takashima A, Kato K, Boku N, Honda K, Yamada T, Hamaguchi T. The peripheral immune status of granulocytic myeloid-derived suppressor cells correlates the survival in advanced gastric cancer patients receiving cisplatin-based chemotherapy. *Oncotarget* 2017; **8**(56): 95083–95094. DOI: [10.18632/oncotarget.18297](https://doi.org/10.18632/oncotarget.18297).
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- 34 Nomura K, Kido M, Tanabe A, Nagashima K, Takenoshita S, Ando K. Investigation of optimal weight gain during pregnancy for Japanese Women. *Scientific Reports* 2017; **7**(1): 2569. DOI: [0.1038/s41598-017-02863-1](https://doi.org/10.1038/s41598-017-02863-1).
- 35 Matsumura T, Terada J, Kinoshita T, Sakurai Y, Yahaba M, Ema R, Amata A, Sakao S, Nagashima K, Tatsumi K, Hiwasa T. Circulating anti-coatomer protein complex subunit epsilon (COPE) autoantibodies as a potential biomarker for cardio- and cerebro-vascular events in patients with obstructive sleep apnea. *Journal of Clinical Sleep Medicine* 2017; **13**(3): 393–400. DOI: [10.5664/jcsm.6488](https://doi.org/10.5664/jcsm.6488).
- 36 Koshizaka M, Ishikawa K, Ishikawa T, Kobayashi K, Takemoto M, Horikoshi T, Shimousa R, Takahashi S, Nagashima K, Sato Y, Tatsuno I, Terano T, Hashimoto N, Kuribayashi N, Uchida D, Yokote K, on behalf of the PRIME-V Study Investigators. Efficacy and safety of ipragliflozin and metformin for visceral fat reduction in type 2 diabetes patients receiving treatment with dipeptidyl peptidase-4 inhibitors in Japan: A study protocol for a prospective, multicenter, blinded-endpoint phase IV randomized controlled trial (PRIME-V study). *BMJ Open* 2017; **7**(5): e015766. DOI: [10.1136/bmjopen-2016-015766](https://doi.org/10.1136/bmjopen-2016-015766).
- 37 Nishimura T, Iwasa S, Nagashima K, Okita N, Takashima A, Honma Y, Kato K, Hamaguchi T, Yamada Y, Shimada Y, Boku N. Irinotecan monotherapy as third-line treatment for advanced gastric cancer refractory to fluoropyrimidines, platinum, and taxanes. *Gastric Cancer* 2017; **20**(4): 655–662. DOI: [10.1007/s10120-016-0670-9](https://doi.org/10.1007/s10120-016-0670-9).

- Yamamoto Y, Yamaguchi S, Sasho T, Fukawa T, Akatsu Y, Akagi R, Yamaguchi T, Takahashi K, Nagashima K, Takahashi K.
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- Yamaguchi N, Misawa S, Sato Y, Nagashima K, Katayama K, Sekiguchi Y, Iwai Y, Amino H, Suichi T, Yokota T, Nishida Y, Kohara N, Hirata K, Nishiyama K, Yabe I, Kaida K-I, Suzuki N, Nodera H, Tsuji S, Koike H, Kira J-I, Hanaoka H, Kusunoki S, Kuwabara S,
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- Misawa S, Sato Y, Katayama K, Nagashima K, Aoyagi R, Sekiguchi Y, Sobue G, Koike H, Yabe I, Sasaki H, Watanabe O, Takashima H, Nishizawa M, Kawachi I, Kusunoki S, Mitsui Y, Kikuchi S, Nakashima I, Ikeda S-i, Kohara N, Kanda T, Kira J-i, Hanaoka H, Kuwabara S, for the Japanese POEMS Syndrome for Thalidomide (J-POST) Trial Study Group. Safety and efficacy of thalidomide in patients with POEMS syndrome: a multicentre, randomised, double-blind, placebo-controlled trial. *The Lancet Neurology* 2016; **15**(11): 1129–1137. DOI: [10.1016/S1474-4422\(16\)30157-0](https://doi.org/10.1016/S1474-4422(16)30157-0).
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- 51 Fujita M, Sato Y, Nagashima K, Takahashi S, Hata A. Validity assessment of self-reported medication use by comparing to pharmacy insurance claims. *BMJ Open* 2015; **5**(11): e009490. DOI: [10.1136/bmjopen-2015-009490](https://doi.org/10.1136/bmjopen-2015-009490).
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- 54 Utsumi H, Honma Y, Nagashima K, Iwasa S, Takashima A, Kato K, Hamaguchi T, Yamada Y, Shimada Y, Kishi Y, Nara S, Esaki M, Shimada K. Bevacizumab and postoperative wound complications in patients with liver metastases of colorectal cancer. *Anticancer Research* 2015; **35**(4): 2255–2261. URL: <http://ar.iiarjournals.org/content/35/4/2255>.
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Tanai C, Nakajima TE, Nagashima K, Kato K, Hamaguchi T, Yamada Y, Muro K, Shirao K, Kunitoh H, Matsumura Y, Yamamoto S,
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randomized clinical chemotherapy trial. *Journal of Oncology Practice* 2011; **7**(3): 148–153. DOI: [10.1200/JOP.2010.000106](https://doi.org/10.1200/JOP.2010.000106).

Hashimoto K, Takashima A, Nagashima K, Okazaki S, Nakajima TE, Kato K, Hamaguchi T, Yamada Y, Shimada Y. Progression-free
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cancer. *Journal of Cancer Research and Clinical Oncology* 2010; **136**(7): 1059–1064. DOI: [10.1007/s00432-009-0752-8](https://doi.org/10.1007/s00432-009-0752-8).

Funding History

Practical research of blood biomarkers for predicting effects of postoperative adjuvant chemotherapies by metastatic activity analysis of non-small cell lung cancer

Co-I

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

April 2017–March 2020

Developing an early-detection and risk-stratification biomarkers for cancer by analyzing post-translational modifications to proteins and peptides

Co-I

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR CANCER RESEARCH AND THERAPEUTIC EVOLUTION (P-CREATE)

April 2017–March 2022

Evaluation study for efficacy and safety of drug therapy based on sex differences

Co-I

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PROJECT FOR WHOLE IMPLEMENTATION TO SUPPORT AND ENSURE THE FEMALE LIFE—WISE

November 2016–March 2019

Development of efficient screening method for early detection and risk stratification of pancreatic cancer

Co-I

JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT, PRACTICAL RESEARCH FOR INNOVATIVE CANCER CONTROL

September 2016–March 2017

Statistical inference for rare event data and its application in clinical researches

PI

JAPAN SOCIETY FOR THE PROMOTION OF SCIENCE (JSPS) KAKENHI, GRANT-IN-AID FOR YOUNG SCIENTISTS (B)
Grant number: 16K16014

April 2016–March 2019

Teaching History

Linear statistical inference

GRADUATE SCHOOL OF ENGINEERING, TOKYO UNIVERSITY OF SCIENCE

Spring 2016–present

Professional Activities

PROFESSIONAL AFFILIATIONS

American Statistical Association

MEMBER

2011–present

The International Biometric Society

MEMBER

2008–present

JOURNAL REVIEWER

Statistics Journal

STATISTICS IN MEDICINE, BIOMETRICAL JOURNAL, STATISTICAL APPLICATIONS IN GENETICS AND MOLECULAR BIOLOGY, JAPANESE JOURNAL OF STATISTICS AND DATA SCIENCE, BEHAVIORMETRIKA

Medical Journal

PLOS ONE, NANOMEDICINE, JOURNAL OF CLINICAL PHARMACY AND THERAPEUTICS

Softwares

pimeta Package

R PACKAGE: PREDICTION INTERVAL FOR RANDOM-EFFECTS META-ANALYSIS; CRAN TASK VIEW: METAANALYSIS

2017

<https://cran.r-project.org/package=pimeta>

ph2bayes Package

R PACKAGE: BAYESIAN SINGLE-ARM PHASE II DESIGNS; CRAN TASK VIEW: EXPERIMENTALDESIGN

2016

<https://cran.r-project.org/package=ph2bayes>

%skmdata

SAS MACRO: A SAS MACRO FOR THE KAPLAN–MEIER PLOT WITH SGPLOT PROCEDURE

2015

<https://github.com/nshi-stat/skmdata>

RcmdrPlugin.KMggplot2 Package

R PACKAGE: GGPLOT2 GUI FRONTEND, R COMMANDER PLUG-IN FOR DATA VISUALIZATION WITH 'GGPLOT2'

2012

<https://cran.r-project.org/package=RcmdrPlugin.KMggplot2>

mmcm Package

R PACKAGE: MODIFIED MAXIMUM CONTRAST METHOD (NAGASHIMA K, ET AL. SAGMB 2011)

2009

<https://cran.r-project.org/package=mmcm>