

業績目録（令和5年）

大学院科目名：生物統計学

(A-b) 和文著書

- 1 手良向聡, 猪原登志子. 第1章臨床試験概論：5. 臨床試験の法的規則, 6. 臨床研究法, 臨床研究の各種規範, 7. 臨床試験の登録制度；第12章その他の臨床試験：77. トランスレーショナルリサーチ, 78. 医療機器の開発. In: 丹後俊郎, 松井茂之編. 臨床試験の事典. 朝倉書店, 東京, 2023:pp16-21, 226-229.
- 2 手良向聡, 山本景一, 河野健一編集. ヘルスデータサイエンス入門：医療・健康データの活用を目指して. 朝倉書店, 東京, 2023.
- 3 手良向聡, 大門貴志監訳. 臨床予測モデル：開発・妥当性確認・更新の手引き. 朝倉書店, 東京, 2023.

(B-b) 和文総説

- 1 手良向聡. 指定発言「第1回21世紀メディカルAIフォーラム：予測科学としての臨床医学のフロンティア」. 臨床評価 2023;51:82-85.
- 2 手良向聡 編. 「ヘルスデータサイエンス学会 第1回学術集会」. 臨床評価 2023;51:188-347.

(C-a) 英文原著

- 1 Senoo K, Yukawa A, Ohkura T, Iwakoshi H, Nishimura T, Shimoo S, Inoue K, Sakatani T, Kakita K, Hattori T, Kitajima H, Nakai K, Nishiuchi S, Nakata M, Teramukai S, Shiraishi H, Matoba S. The impact of home electrocardiograph measurement rate on the detection of atrial fibrillation recurrence after ablation: A prospective multicenter observational study. *International Journal of Cardiology Heart & Vasculature* 2023;44:101177. doi: 10.1016/j.ijcha.2023.101177. (IF=2.5)
- 2 Mukai M, Hamano A, Mizuta I, Yokota I, Watanabe-Hosomi A, Matsuura H, Koizumi T, Matsuura J, Ohara T, Matsushima S, Teramukai S, Yamada K, Mizuno T. Association between cerebrovasoreactivity and stroke in cerebral autosomal dominant arteriopathy with subcortical

- infarcts and leukoencephalopathy. *Frontiers in Neurology* 2023;13:1087220. doi: 10.3389/fneur.2022.1087220. (IF=2.7)
- 3 Nagata K, Inoue H, Yamashita T, Akao M, Atarashi H, Ikeda T, Koretsune Y, Okumura K, Shimizu W, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Yasaka M. Impact of cognitive impairment on clinical outcomes in elderly patients with atrial fibrillation: ANAFIE Registry. *BMJ Neurology Open* 2023;5:e000370. doi: 10.1136/bmjno-2022-000370. (IF=2.1)
 - 4 Suzuki S, Yamashita T, Akao M, Atarashi H, Ikeda T, Okumura K, Koretsune Y, Shimizu W, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Clinical phenotypes of older adults with non-valvular atrial fibrillation not treated with oral anticoagulants by hierarchical cluster analysis in ANAFIE registry. *PLoS One* 2023;18:e0280753. doi: 10.1371/journal.pone.0280753. (IF=2.9)
 - 5 Ikeda T, Yamashita T, Akao M, Atarashi H, Koretsune Y, Okumura K, Shimizu W, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Prognostic impact of heart rate during atrial fibrillation on clinical outcomes in elderly non-valvular atrial fibrillation patients: ANAFIE Registry sub-cohort study. *Journal of Cardiology* 2023;81:441-449. doi: 10.1016/j.jjcc.2022.11.011. (IF=2.5)
 - 6 Kato M, Horiguchi G, Ueda T, Fujihara A, Hongo F, Okihara K, Marunaka Y, Teramukai S, Ukimura O. A big data-based prediction model for prostate cancer incidence in Japanese men. *Scientific Reports* 2023;13:6579. doi: 10.1038/s41598-023-33725-8. (IF=3.8)
 - 7 Ogawa K, Khan KN, Koshiha A, Fujishita A, Horiguchi G, Teramukai S, Itoh K, Guo SW, Mori T. Association between tissue stress reaction and ACE2/TMPRSS2 expression in endometria of reproductive aged women before and during Covid-19 pandemic. *BMC Women's Health* 2023;3:229. doi: 10.1186/s12905-023-02378-0. (IF=2.4)
 - 8 Takeuchi S, Kubota K, Sugawara S, Teramukai S, Noro R, Fujikawa K, Hirose T, Atagi S, Minami S, Iida S, Kuraishi H, Aiba T, Minegishi Y, Matsumoto M, Seike M, Gemma A, Kawahara M, Japan-Multinational Trial Organization (JMTO). Standard versus low-dose nab-paclitaxel

- in previously treated patients with advanced non-small cell lung cancer: A randomized phase II trial (JMT0 LC14-01). *Cancer Medicine* 2023;12:9133-9143. doi: 10.1002/cam4.5652. (IF=2.9)
- 9 Yamazaki S, Numata S, Kawajiri H, Manabe K, Ikemoto K, Teramukai S, Yaku H. Effect of left ventricular hyperenhancement in magnetic resonance imaging on reverse remodeling after mitral valve repair for moderate ischemic mitral regurgitation. *Seminars in Thoracic and Cardiovascular Surgery* 2023;35:239-248. doi: 10.1053/j.semtcvs.2022.02.007. (IF=2.6)
- 10 Yamazaki H, Kimoto T, Teramukai S, Fujikawa K, Shibuya K, Suzuki M, Terashima K, Iizumi T, Wakatsuki M, Suzuki O, Fukumoto T, Ohtsuka M. Particle beam therapy versus photon radiotherapy for extrahepatic biliary cancer - systemic review and meta-analysis. *Journal of Radiation Research* 2023;64:i34-i40. doi: 10.1093/jrr/rrad015. (IF=1.9)
- 11 Aibe N, Ogino H, Wakatsuki M, Fujikawa K, Teramukai S, Fukumitsu N, Shiba S, Yamamoto N, Nomoto A, Ono T, Oguri M, Yamaguchi H, Numajiri H, Shibuya K, Okazaki S, Miyasaka Y, Okonogi N, Murata K, Takebe H, Motegi A, Okimoto T, Yoshino T, Mandai M, Katoh N, Tsuji H, Sakurai H. Comprehensive analysis of Japanese nationwide cohort data of particle beam therapy for pulmonary, liver, and lymph node oligometastases: particle beam therapy versus high-precision X-ray radiotherapy. *Journal of Radiation Research* 2023;64:i69-i83. doi: 10.1093/jrr/rrad004. (IF=1.9)
- 12 Hironaka J, Okada H, Hamaguchi M, Sakai K, Minamida M, Kondo Y, Hashimoto Y, Kitagawa N, Yano M, Yamazaki M, Hasegawa G, Horiguchi G, Teramukai S, Fukui M. Effects of dapagliflozin on renal function in type 1 diabetes patients in the real world: A retrospective multicenter study of the KAMOGAWA-A cohort. *Diabetes Research and Clinical Practice* 2023:110794. doi: 10.1016/j.diabres.2023.110794. (IF=6.1)
- 13 Ogawa K, Khan KN, Kuroboshi H, Koshiba A, Shimura K, Tajiri T, Fumino S, Fujita H, Okubo T, Fujiwara Y, Horiguchi G, Teramukai S, Fujishita A, Itoh K, Guo SW, Kitawaki J, Mori T. Is neonatal uterine bleeding responsible for early-onset endometriosis?

- Reproductive Biology and Endocrinology 2023;21:56. doi:
10.1186/s12958-023-01099-1. (IF=4.2)
- 14 Kawamura T, Sekiguchi M, Takamaru H, Mizuguchi Y, Horiguchi G, Kato M, Kobayashi K, Sada M, Oda Y, Yokoyama A, Utsumi T, Tsuji Y, Oki D, Takeuchi Y, Shichijo S, Ikematsu H, Matsuda K, Teramukai S, Matsuda T, Saito Y, Tanaka K. “Endoscopic” adenoma detection rate as a quality indicator of colonoscopy: First report from the J-SCOUT study. *Digestive Endoscopy* 2023;35:615-624. doi:
10.1111/den.14483. (IF=5.0)
- 15 Shimizu W, Yamashita T, Akao M, Atarashi H, Ikeda T, Koretsune Y, Okumura K, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Renal function and clinical outcomes among elderly patients with nonvalvular atrial fibrillation from ANAFIE. *JACC Asia* 2023;3:475-487. doi: 10.1016/j.jacasi.2023.02.002. (IF=なし)
- 16 Yamashita T, Akao M, Atarashi H, Ikeda T, Koretsune Y, Okumura K, Shimizu W, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Causes of death in elderly patients with non-valvular atrial fibrillation: Results from the ANAFIE Registry. *Circulation Journal* 2023;87:957-963. doi: 10.1253/circj.CJ-22-0614. (IF=3.1)
- 17 Ueta M, Inoue C, Nakata M, Sotozono C, Kim MK, Wakamatsu T, Jongkhajornpong P, Saeed H, Rauz S, Hui-Kang Ma D, Yoon KC, Puangsricharern V, Bouchard C, Ahmad S, Seo KY, Joo CK, Jose Alvaro Pereira Gomes, James Chodosh, Kinoshita S, Teramukai S. Severe ocular complications of SJS/TEN and associations among pre-onset, acute, and chronic factors: a report from the international ophthalmology collaborative group. *Frontier in Medicine (Lausanne)* 2023;10:1189140. doi: 10.3389/fmed.2023.1189140. (IF=3.1)
- 18 Terauchi Y, Inoue H, Yamashita T, Akao M, Atarashi H, Ikeda T, Koretsune Y, Okumura K, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Shimizu W. Impact of glycated hemoglobin on 2-year clinical outcomes in elderly patients with atrial fibrillation: sub-analysis of ANAFIE Registry, a large observational study. *Cardiovascular Diabetology* 2023;22:175. doi: 10.1186/s12933-023-01915-3. (IF=8.5)

- 19 Akao M, Yamashita T, Atarashi H, Ikeda T, Koretsune Y, Okumura K, Shimizu W, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Comprehension of nonvalvular atrial fibrillation and anticoagulant adherence in elderly patients in subcohort study of the All Nippon Atrial Fibrillation in the Elderly Registry. *American Journal of Cardiology* 2023;204:159-167. doi: 10.1016/j.amjcard.2023.06.086. (IF=2.3)
- 20 Koretsune Y, Yamashita T, Akao M, Atarashi H, Ikeda T, Okumura K, Shimizu W, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Coagulation biomarkers and clinical outcomes in elderly patients with non-valvular atrial fibrillation: ANAFIE sub-cohort study. *JACC Asia* 2023;3:595-607. doi: 10.1016/j.jacasi.2023.06.004. (IF=2.3)
- 21 Fujioka A, Yanishi K, Yukawa A, Imai K, Yokota I, Fujikawa K, Yamada A, Naito A, Shoji K, Kawamata H, Higashi Y, Ishigami T, Sasaki K, Tara S, Kuwahara K, Teramukai S, Matoba S. A multicenter prospective interventional trial of therapeutic angiogenesis using bone marrow-derived mononuclear cells implantation for patients with critical limb-threatening ischemia caused by thromboangiitis obliterans. *Circulation Journal* 2023;87:1229-1237. doi: 10.1253/circj.CJ-23-0046. (IF=3.1)
- 22 Shiozawa M, Koga M, Inoue H, Yamashita T, Yasaka M, Suzuki S, Akao M, Atarashi H, Ikeda T, Okumura K, Koretsune Y, Shimizu W, Tsutsui H, Hirayama A, Nakahara J, Teramukai S, Kimura T, Morishima Y, Takita A, Yamaguchi T, Toyoda K. Risk of both intracranial hemorrhage and ischemic stroke in elderly individuals with nonvalvular atrial fibrillation taking direct oral anticoagulants compared with warfarin: Analysis of the ANAFIE registry. *International Journal of Stroke* 2023;18:986-995. doi: 10.1177/17474930231175807. (IF=6.3)
- 23 Tsujio Y, Yasuda M, Hattori M, Yoshida T, Nakamura N, Nakata M, Teramukai S, Minemura Y, Azuma T. Developing a behaviour rubric for the practical model of ethical behavior for clinical nursing. *Nursing Open* 2023;10:7382-7393. doi: 10.1002/nop2.1992. (IF=2.0)

- 24 Takai A, Yamagishi M, Ikeda K, Sugimoto A, Ichise E, Maeda Y, Teramukai S, Hasegawa T, Oda S, Iehara T. Effectiveness of cardiac palliative surgery for trisomy 18 patients with increased pulmonary blood flow. *American Journal of Medical Genetics Part A* 2023;191A:2703–2710. doi: 10.1002/ajmg.a.63401. (IF=1.7)
- 25 Yashige M, Inoue K, Zen K, Kobayashi R, Nakamura S, Fujimoto T, Takamatsu K, Sugino S, Yamano M, Yamano T, Nakamura T, Doman T, Teramukai S, Horiuchi H, Itoh Y, Matoba S. Gastrointestinal angiodysplasia before and after treatment of severe aortic stenosis. *New England Journal of Medicine* 2023;389:1530–1532. doi: 10.1056/NEJMc2306027. (IF=96.2)
- 26 Akao M, Inoue H, Yamashita T, Atarashi H, Ikeda T, Koretsune Y, Okumura K, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Shimizu W. Relationships between direct oral anticoagulant doses and clinical outcomes in elderly patients with non-valvular atrial fibrillation: ANAFIE registry sub-analysis. *Circulation Journal* 2023;87:1765–1774. doi: 10.1253/circj.CJ-23-0143. (IF=3.1)
- 27 Kario K, Hasebe N, Okumura K, Yamashita T, Akao M, Atarashi H, Ikeda T, Koretsune Y, Shimizu W, Suzuki S, Tsutsui H, Toyoda K, Hirayama A, Yasaka M, Yamaguchi T, Teramukai S, Kimura T, Morishima Y, Takita A, Inoue H. Anticoagulant therapy and home blood pressure-associated risk for stroke/bleeding events in elderly patients with non-valvular atrial fibrillation: the sub-cohort study of ANAFIE Registry. *Hypertension Research* 2023;46:2575–2582. doi: 10.1038/s41440-023-01361-4. (IF=4.3)
- 28 Sato K, Horiguchi G, Teramukai S, Yoshida T, Shimizu F, Hashimoto N. Time-of-flight magnetic resonance angiography for detection of postoperative recurrence in patients with chronic subdural hematoma. *Acta Neurologica Belgica* 2023;123:2167–2175. doi: 10.1007/s13760-022-02154-1. (IF=2.0)
- 29 Nishi M, Seki T, Shikuma A, Kawamata H, Horiguchi G, Matoba S. Association between patient volume to cardiologist, process of care, and clinical outcomes in heart failure. *ESC Heart Failure*. 2023;10:2262–2268. doi:10.1002/ehf2.14385. (IF=3.2)

(C-b) 和文原著

- 1 手良向聡. ベイズ流臨床試験における標本サイズ設定：2つの事前分布を用いた推論上の性能に基づく接近法. 計量生物学 2023;44:35-51.
- 2 合田武司, 平山圭, 堀口剛, 森潤, 木原明生. 成長障害を伴う中枢性先天性甲状腺機能低下症に対するホルモン補充の成長率改善効果. 日本小児科学会雑誌 2023;127:1505-1512.

(D) 学会発表等

II) シンポジウム、ワークショップ、パネルディスカッション等

- 1 手良向聡. 試験統計家認定制度の紹介. ARO 協議会第 10 回学術集会. 若手企画「試験統計家のすゝめ? - ARO における資格について考えてみる -」, 2023, 東京.
- 2 手良向聡. 臨床予測モデルの開発と妥当性確認. 2023 年度統計関連連合大会企画セッション「個別化医療に向けたヘルスデータサイエンスの実践：臨床予測モデルの最前線」, 2023, 京都.
- 3 手良向聡. アダプティブ臨床試験デザイン. 神戸大学臨床研究推進セミナー, 2023, WEB 開催.
- 4 手良向聡. 臨床試験におけるランダム化の意義. 2023 年度第 1 回臨床統計シンポジウム「臨床試験において外部対照をどう選ぶか」, 2023, WEB 開催.
- 5 手良向聡. 臨床試験を哲学する. 京都女子大学データサイエンス研究所第 1 回データサイエンス統計領域シンポジウム, 2023, 京都.

E 研究助成（競争的研究助成金）

総額 240 万円

公的助成

代表（総額）・小計 50 万円

- 1 中田美津子：日本学術振興会科学研究費助成事業 研究活動スタート支援
令和 5 年度
心房細動に対する体系的スクリーニングの費用対効果分析
助成金額 50 万円

分担・小計 190 万円

- 1 手良向聡：日本医療研究開発機構・医療機器開発推進研究事業
令和 3 年～令和 5 年度

医療費適正化に資する前立腺癌病巣標的化凍結治療：医師主導治験

- 2 手良向聡：日本医療研究開発機構・難治性疾患実用化研究事業
令和3年～令和5年度
SJS/TEN 眼合併症の診断および治療の質的向上に関する実践的研究
助成金額 90 万円

- 3 手良向聡：日本医療研究開発機構・医療研究開発革新基盤創成事業
令和5年～令和10年度
世界初のイントラクライン機構を介したマイボーム腺機能不全治療薬の
開発
助成金額 100 万円