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• **別紙**

- 別紙 1：治験実施体制一覧

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1. 治験実施医療機関および自ら治験を実施する者（治験責任医師）

京都大学医学部附属病院

治験責任医師（自ら治験を実施する者） 血液・腫瘍内科 助教 菱澤 方勝

〒606-8507 京都府京都市左京区聖護院川原町 54

TEL : 075-751-3152 FAX : 075-751-3153

佐賀大学医学部附属病院

治験責任医師（自ら治験を実施する者）

〒849-8501 佐賀市鍋島五丁目 1番 1号

TEL : 0952 - XX- XXXX FAX : 0952 - XX- XXXX

長崎大学病院

治験責任医師（自ら治験を実施する者）

〒852-8501 長崎県長崎市坂本1丁目 7番 1号

TEL : 095- XXX- XXXX FAX : 095- XXX- XXXX

【主な業務内容】

- 実施医療機関における本治験に係わる業務を統括するとともに、チームの責任者として治験分担医師、治験協力者等を管理・指導し、以下の業務を行う。
- 治験実施計画書の合意及びその遵守
- 説明文書および同意文書の作成および改訂
- 治験審査委員会への文書提出
- 被験者の選定および同意の取得
- 被験者に対する適切な医療
- 治験実施計画書からの逸脱の記録およびその提出
- 症例報告書の作成及び報告
- 治験中止時の報告
- モニタリングおよび監査への協力
- 有害事象の報告
- 治験に係る文書または記録の保管

様式第19

学会等発表実績

委託業務題目「疾患特異的iPS細胞を活用した特発性造血障害の病態解析と新規治療法開発」

機関名 京都大学医学研究科血液・腫瘍内科学・京都大学医学部附属病院臨床研究総合センター

1. 学会等における口頭・ポスター発表

発表した成果（発表題目、口頭・ポスター発表の別）	発表者氏名	発表した場所（学会等名）	発表した時期	国内・外の別
A screening for DNA repair enzymes related to HIV-1 life cycle (poster)	Yoshinaga N, Matsui Y, Shindo K, Takiuchi Y, Tada K, Takeda S, Takaori-Kondo A	Cold Spring Harbor meeting on Retroviruses	2014/5/19-24	国外
CBF β stabilizes HIV-1 Vif by inhibiting MDM2-mediated degradation (poster)	Matsui Y, Shindo K, Nagata K, Yoshinaga N, Maruyama W, Shirakawa K, Kobayashi M, Takaori-Kondo A	Cold Spring Harbor meeting on Retroviruses	"	国外
Anti-lactoferrin autoantibodies contribute to the pathogenesis of IgG4 related disease by inducing neutrophil extracellular trap formation (poster)	Arai Y, Yamashita K, Mizugishi K, Takaori-Kondo A	Annual European Congress of Rheumatology EULAR 2014	2014/6/11-15	国外
Human DCs with high retinoic acid-producing capacity (poster)	Sato T, Kitawaki T, Fujita H, Iwata M, Iyoda T, Inaba K, Ohteki T, Takaori-Kondo A, Kadowaki N	the 13th International Symposium on Dendritic Cells	2014/9/14-18	国外
The Pharmacological Inhibition of KDM1A Displays Preclinical Efficacy in AML and MDS By Inducing Myelomonocytic Differentiation (poster)	Sugino N, Kawahara M, Suzuki T, Nagai Y, Shimazu Y, Fujii S, Yamamoto R, Hishizawa M, Takaori-Kondo A	The 56th ASH Annual Meeting and Exposition	2014/12/6-9	国外

Expression of Tim-1 and Its Pathogenetic Role in Primary CNS Lymphoma (poster)	Nishikori M, Kishimoto W, Arima H, Shirakawa K, Kitawaki T, Takaori- Kondo A	The 56th ASH Annual Meeting and Exposition	2014/12/6-10	国外
Landscape of Genetic Alterations in Adult T-Cell Leukemia/Lymphoma (口演)	Kataoka K, Nagata Y, Kitanaka A, Totoki Y, Yasunaga J-i, Kotani S, Sato-Otsubo A, Sanada M, Shiraishi Y, Shimamura T, Chiba K, Tanaka H, Suzuki H, Sato Y, Shiozawa Y, Yoshizato T, Kon A, Yoshida K, Hishizawa M, Munakata W, Nakamura H, Hama N, Shide K, Kubuki Y, Hidaka T, Kameda T, Ishiyama K, Miyawaki S, Ishii R, Nureki O, Nagae G, Aburatani H, Miyano S,	The 56th ASH Annual Meeting and Exposition	2014/12/6-11	国外
Patient-Specific Induced Pluripotent Stem Cells Recapitulate the Maturation Defect of Myelodysplastic Syndromes (poster)	Chonabayashi K, Kawahara M, Okita K, Nishizawa M, Kadowaki N, Takaori- Kondo A, Yamanaka S, Yoshida Y	The 56th ASH Annual Meeting and Exposition	2014/12/6-12	国外
Presepsin (soluble CD14 subtype) Is Secreted from Human Monocytes after Phagocytosis - in Vitro Analyses and a Retrospective Cohort Study in Patients with Allogeneic Stem Cell Transplantation (poster)	Arai Y, Yamashita K, Mizugishi K, Takaori- Kondo A	The 56th ASH Annual Meeting and Exposition	2014/12/6-12	国外
Functional Interaction between APOBEC3 and HIV-1 Vif (口演)	Takaori- Kondo A	17th International Conference on Emerging Infectious Diseases Taipei	2015/1/28-29	国外

A Screening for DNA Repair Enzymes That Affect HIV-1 Infection (poster)	Yoshinaga N, Matsui Y, Shindo K, Takeda S, Takaori- Kondo A	Conference on Retroviruses and Opportunistic Infections 2015	2015/2/23-26	国外
KDM1A is a promising therapeutic target of myelodysplastic syndromes.	Noriko Sugino,	第76回日本血液学会学術集会 大阪	Oct31-Nov2, 2014	国内
iPS technology revealed the genetic and functional diversity present in a single MDS patient	Kazuhisa Chonabayashi, Masahiro Kawahara, Keisuke Okita, Masatoshi Nishizawa, Norimitsu Kadowaki, Akifumi Takaori- Kondo, Shinya Yamanaka, and Yoshinori Yoshida	第76回日本血液学会学術集会 大阪	Oct31-Nov2, 2014	国内

2. 学会誌・雑誌等における論文掲載

掲載した論文（発表題目）	発表者氏名	発表した場所 (学会誌・雑誌等名)	発表した時期	国内・外の別
Ratio of peripheral blood absolute lymphocyte count to absolute monocyte count at diagnosis is associated with progression-free survival in follicular lymphoma	Kumagai S, Tashima M, Fujikawa J, Iwasaki M, Iwamoto Y, Sueki Y, Fukunaga A, Yanagita S, Nishikori M, Takaori- Kondo A, Arima N	International Journal of Hematology	2014/4/24	国外
Plasmacytic ALK-positive large B-cell lymphoma: A potential mimic of extramedullary plasmacytoma	Hashimoto T, Fujimoto M, Nishikori M, Takeuchi K, Kimura M, Nakajima N, Miyagawa- Hayashino A, Takaori- Kondo A, Haga H	Pathology International	2014/6/27	国外

Small molecules that inhibit Vif-induced degradation of APOBEC3G	Matsui M, Shindo K, Izumi T, Io K, Shinohara M, Komano J, Kobayashi M, Kadowaki N, Harris RS, Takaori- Kondo A	Virology Journal	2014/7/6	国外
Risk factors for late-onset neutropenia after rituximab treatment of B-cell lymphoma	Arai Y, Yamashita K, Mizugishi K, Nishikori M, Hishizawa M, Kondo T, Kitano T, Kawabata H, Kadowaki N, Takaori- Kondo A	Hematology	2014/8/19	国外
RING-mutant Mdm2-M459I Confers Anti-apoptotic Effect in Primary Cells	Mikawa T, LLeonart ME, Takaori- Kondo A, Yokode M, Kondoh H	Journal of Cytology & Histology	2014/10/3	国外
APOBEC3D and APOBEC3F Potently Promote HIV-1 Diversification and Evolution in Humanized Mouse Model	Sato K, Takeuchi JS, Misawa N, Izumi T, Kobayashi T, Kimura Y, Iwami S, Takaori- Kondo A, Hu WS, Aihara K, Ito M, An DS, Pathak VK, Koyanagi Y	PLoS Pathogens	2014/10/21	国外

	Kobayashi T, Kuroda J, Fuchida S, Kaneko H, Yagi H, Shibayama H, Tanaka H, Kosugi S, Uoshima N, Kobayashi M, Adachi Y, Ohta K, Ishii K, Uchiyama H, Matsuda M, Nakatani E, Tsudo M, Shimazaki C, Takaori- Kondo A, Nomura S, Matsumura I, Taniwaki M, Kanakura Y	International Journal of Hematology	2014/11/12	国外
Monitoring mycophenolate mofetil is necessary for the effective prophylaxis of acute GVHD after cord blood transplantation	Arai Y, Kondo T, Kitano T, Hishizawa M, Yamashita K, Kadowaki N, Yamamoto T, Yano I, Matsubara K, Takaori- Kondo A	Bone Marrow Transplantation	2014/11/12	国外
Sphingolipid Pathway Regulates Innate Immune Responses at the Feto-maternal Interface during Pregnancy	Mizugishi K, Inoue T, Hatayama H, Bielawski J, Pierce JS, Sato Y, Takaori- Kondo A, Konishi I, Yamashita K	The Journal of Biological Chemistry	2014/12/17	国外
Dysregulated glycolysis as an oncogenic event	Mikawa T, ME LL, Takaori- Kondo A, Inagaki N, Yokode M, Kondoh H	Cellular and Molecular Life Sciences	2015/1/23	国外
Sensitive and validated LC-MS/MS methods to evaluate mycophenolic acid pharmacokinetics and pharmacodynamics in hematopoietic stem cell transplant patients	Kawanishi M, Yano I, Yoshimura K, Yamamoto T, Hashi S, Masuda S, Kondo T, Takaori- Kondo A, Matsubara K	Biomedical Chromatography	2015/1/28	国外

A HAMP promoter bioassay system for identifying chemical compounds that modulate hepcidin expression	Kawabata H, Uchiyama T, Sakamoto S, Kanda J, Oishi S, Fujii N, Tomosugi N, Kadowaki N, Takaori- Kondo A	Experimental Hematology	2015/1/31	国外
Effects of zoledronic acid and the association between its efficacy and $\gamma\delta T$ cells in postmenopausal women with breast cancer treated with preoperative hormonal therapy: a study protocol.	Sumi E, Sugie T, Yoshimura K, Tada H, Ikeda T, Suzuki E, Tanaka Y, Teramukai S, Shimizu A, Toi M, Minato N	Journal of Translational Medicine	2015/11/25	国外
A randomized controlled clinical trial of topical insulin-like growth factor-1 therapy for sudden deafness refractory to systemic corticosteroid treatment.	Nakagawa T, Kumakawa K, Usami S, Hato N, Tabuchi K, Takahashi M, Fujiwara K, Sasaki A, Komune S, Sakamoto T, Hiraumi H, Yamamoto N, Tanaka S, Tada H, Yamamoto M, Yonezawa A, Ito-Ihara Toshiko, Ikeda T, Shimizu A, Tabata Y, Ito J	BMC Medicine	2015/11/19	国外
A continual reassessment method with cohort size adaptation based on Bayesian posterior probabilities in phase I dose-finding studies.	Kakizume T, Morita S	Therapeutic Innovation & Regulatory Science	2015/3/3	国外
Exploring ethnic differences in toxicity in early phase clinical trials for oncology drugs.	Ogura T, Morita S, Yonemori K, Nonaka T, Urano T	Therapeutic Innovation & Regulatory Science	2015/9/10	国外

Survival of HER2-positive primary breast cancer patients treated by neoadjuvant chemotherapy plus trastuzumab: a multicenter retrospective observational study (JBCRG-C03 study).	Takada M, Ishiguro H, Nagai S, Ohtani S, Kawabata H, Yanagita Y, Hozumi Y, Shimizu C, Takao S, Sato N, Kosaka Y, Sagara Y, Iwata H, Ohno S, Kuroi K, Masuda N, Yamashiro H, Sugimoto M, Kondo M, Naito Y, Sasano H, Inamoto T, Morita S, Toi M	Breast Cancer Res Treat	2015/3/30	国外
Biomarker-based Bayesian randomized phase II clinical trial design to identify a sensitive patient subpopulation.	Morita S, Yamamoto H, Sugitani Y	Stat Med	2015/5/13	国外
Incorporating historical data in Bayesian phase I trial design: The Caucasian-to-Asian toxicity tolerability problem.	Takeda K, Morita S.	Therapeutic Innovation & Regulatory Science [Epub ahead of print]	(in press)	

