

巻頭言【巻頭言 web 版あり】

栗原 雅直

1. 生命倫理と研究倫理の過去・現在・未来（第2回）

●臨床研究の信頼性と公正性

1. 原著：臨床試験の信頼性確保のために－ICH-GCP（R2）と日本における臨床研究
 法案をめぐる考察－ 河野 健一
2. 資料：第190回国会（常会）に提出された臨床研究法案第3条に（一財）医薬品医療機器レギュラトリ
 規定する「臨床研究実施基準」等に関する提言について ーサイエンス財団
3. 論説：粉飾された臨床試験の判別法：臨床試験のすべての関係者へ 奥村 泰之

●フランス第I相被験者死亡事故：「レンヌ事件」について

4. 総説：レンヌ事件の教訓 熊谷 雄治，門間 毅
5. 原著：「レンヌ事件」について－フランスにおける第I相試験死亡事故の教訓 栗原千絵子，齊尾 武郎，
 櫛島 次郎

●研究対象者保護プログラムの最新動向

6. インタビュー：米国AAHRPP（研究対象者保護プログラム認証協会）Dr. Elyse Elyse I. Summers, Sarah
 I. Summers（会長・CEO），Dr. Sarah H. Kiskaddon（Director・Public H. Kiskaddon
 Affairs）インタビュー：米国と世界の被験者保護システムの最近の動向 インタビュー：栗原千絵子
7. 解説：韓国における「臨床試験と対象者保護プログラムガイドライン」 栗原千絵子，李 侖珍
 について
8. 翻訳：臨床試験対象者保護プログラム（HRPP）運営ガイドライン 韓国食品医薬品安全省
 李 侖珍，栗原千絵子，訳

2. 2nd Taiwan-Japan Academic Research Organization Workshop－Cancer translational research and
 cancer registry studies－

Supportive platform/infrastructure ; Opening remarks

1. Welcome and opening remarks; Infrastructure and activity of biotechnology development in Taiwan Pan-Chyr Yang
2. ARO's strategy and actions in translational research Yoichi Nakanishi
3. Welcoming remarks Andrew H.-J. Wang

Session I : Mental diseases

4. Novel therapeutics for mental disorders and Alzheimer's disease: Consortium for Mental Disorders (CMD) Hsien-Yuan Lane
5. Elucidate the etiopathology of mental disorders: To overcome the psychopharmacology in crisis Norio Ozaki

Session II : Oncology 1

6. Oncology Phase I Consortium and international collaboration Josh Chia-Chi Lin
7. Early clinical development in EPOC (NCC & NCCE) Toshihiko Doi
8. Clinical and translation research for lung cancer in Taiwan James Chih-Hsin Yang
9. A nationwide genomic screening project in Japan (LC-SCRUM-Japan) Koichi Goto

Session III : Oncology 2 & cancer registry

10. GI Disease Consortium & designing reliable therapy for mass eradication of H. pylori to prevent gastric cancer in Taiwan Ming-Shiang Wu
11. Precision epigenetic risk diagnosis after mass eradication of H. pylori Toshikazu Ushijima
12. Investigator-Initiated Trials and translational research in NICR/TCOG－Focusing on non-CRC GI Cancers Li-Tzong Chen

13. Continuous regional arterial infusion (CRAI) versus venous infusion of nafamostat mesylate for severe acute pancreatitis: Background and study protocol for a multicenter randomized controlled trial by a Japanese study group
Moriyama Hirota
14. Registry and biobank for rare cancer in Japan: Gastrointestinal stromal tumor, sarcoma and neuroendocrine tumor
Toshiro Nishida
- Session IV : Oncology 3**
15. Early cancer drug discovery and development in academic setting clinical development in EPOC (NCC & NCCE)
Yun Yen
16. New strategy for cancer immunotherapy
Yasufumi Kaneda
17. Nano-cancer: From nano scale molecular structure and dynamic analysis to new therapeutics and theranostics engineering
Dar-Bin Shieh
18. Immune-escape polymeric micelles carrying radionuclides as theranostic agent for breast cancer
Shunsaku Kimura
19. Developing novel cancer imaging in Taiwan
Yeun-Chung Chang
20. PET screening study for early detection of cancer and its long-term follow-up
Shinsuke Kojima
21. Current status for the surgery of colorectal cancer in Taiwan
Jin-Tung Liang
22. Standardization of colon cancer surgery
Kenichi Sugihara
- Session V : Oncology 4 & biobanking**
23. Drug development for hepatocellular carcinoma in Taiwan: A decade of evolution
Ann-Lii Cheng
24. The present and future of Taiwanese Gynecologic Oncology Group (TGOG)
Kung-Liang Wang
25. JGOG's activities
Aikou Okamoto
26. Taiwan Biobank for the health of the next generations
Chen-Yang Shen
27. Biobank and informatics for cancer projects and clinical sequencing at Kyoto University Cancer Center
Manabu Muto
28. General discussion organization
Fu-Tong Liu
- 3. ASIAARO Network Workshop—The 4th Annual Japan ARO Council Meeting: Global ARO Network building—**
- Opening remarks**
1. Opening remarks
Akira Myoui
- ARO structure, functions and activities in Korea**
2. Structure, functions, and activities of Medical Research Collaborating Center
Han-Suk Kim,
Joongyub Lee
3. ARO at Asan Medical Center—Collaboration with local AROs
Beck Sung Ho
4. KoNECT and KoNECT Collaboration Center: Fostering global clinical development in Korea
Deborah Chee
5. Mutual use of e-IRB system for Korea-Japan Research Cooperation
Hyunin Cho,
Younjin Rhee
- ARO structure, functions and activities in Taiwan**
6. Structure, functions and activities of NRPB in Taiwan
Ming-Shiang Wu
7. Taiwan Biobank and Biosignature Consortia
Fu-Tong Liu
- ARO structure, functions and activities in Singapore**
8. Singapore ARO structure and research operational strategy
Damien Hong Yew Hui
- Japan ARO network: Activity and achievements**
9. Overview of Japanese ARO Network
Yoichi Nakanishi
10. Supporting system for translational research and medical innovation in
Kiyoshi Okada

Osaka University Hospital

11. New oncology agents development in NCC

Atsushi Ohtsu

12. ARO activity and achievements of Tohoku University Hospital

Tadao Takano

●Discussion and closing remarks

13. Closing remarks

Masanori Fukushima

4. 訃報

1. 清水直容先生を悼む

栗原 雅直

編集後記【web版あり】

津谷喜一郎

5. Web版【web版のみ】

1. Interview : Interview with Dr. Elyse I. Summers, President & CEO, and Dr. Sarah H. Kiskaddon, Director of Global Development & Public Affairs, Association for the Accreditation of Human Research Protection Program (AAHRPP) – Recent trend of human subject protection system in U.S. and in the world –

Elyse I. Summers, Sarah H. Kiskaddon
Interview : Chieko Kurihara

申込み先 FAX : 03-5489-6517 / e-mail : cont@nifty.com

各特集号 定価 : 5,000 円 ; アカデミア 3,000 円 十税・送料

4月10日(月)お申込みまで確実にご提供できます。その後は、在庫がある限りのご提供となります。

「臨床評価」他の号のご案内 : <http://cont.o.oo7.jp/specialissue.html>

■申込み書

45-1 広報 HP

●購入希望号を明記の上、ご希望冊数をご記入ください :

●お名前・ご所属 :

●送付先ご住所〔請求書の御宛名が上記と異なる場合は明記してください〕 :

●ご連絡先 (tel, fax, e-mail) :