臺灣臨床試驗生統中心，培訓中心，與藥物基因體實驗室

Taiwan Clinical Trial Statistical Center, Training Center, and Pharmacogenomics Laboratory

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轉譯醫學與臨床試驗電子報

Translational Medicine and Clinical Trial E-paper

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內容搶先看

一、臨床試驗教育訓練活動

1. 「PTMS*使用教育訓練」
   課程內容：如何使用臨床研究資訊系統來執行臨床研究或試驗
   時間：2015 年 4 月 22 日 14:00~17:00
   報名網址：http://www.cims.tw/ch/trainingreg

2. 「CSIS*使用教育訓練」
   課程內容：如何應用 PTMS 控管計畫審核作業
   時間：2015 年 4 月 29 日 10:30~11:30
   地點：高雄-榮民總醫院
   報名網址：http://www.cims.tw/ch/trainingreg

*: CSIS: 臨床研究資訊系統; PTMS: (臨床試驗) 計畫追蹤與管理系統

對臨床研究或試驗有興趣之人員，請不要錯過這次機會，名額有限，歡迎各位踴躍報名！

二、臨床試驗研討會

Joint COS-CAHON-SITC Workshop on Cancer Immunotherapy 2015

The interaction between the immune system and cancer cells has long been recognized and now there is growing evidence that recent results from clinical trials are leading to exciting new therapeutic possibilities for cancer patients. As a result, we will hold a workshop on cancer immunotherapy on April 25, 2015 in Taipei, Taiwan to promote the basic understanding of and discuss the potential problems of cancer immunotherapy among the oncology

Conference Date

April 25 (Sat), 2015

Conference Venue

NTUH International Convention Center
(http://www.nthcc.com.tw/en/about04.htm)
Auditorium 301, No. 2 Xuzhou Rd, Taipei 100, Taiwan

Agenda (Tentative)

Time	Topic	Moderator
08:30-09:00 AM	Registration	
09:00-09:10 AM	Opening Remark Ann-Lii Cheng, National Taiwan University Hospital, Taipei, Taiwan Yun Yen, Taipei Medical University, Taipei, Taiwan	
09:10-09:40 AM	The Transformation of Oncology: A Strategic Review of Immunoscore and Immunotherapy Bernie Fox SITC/Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute, Providence Cancer Center, Portland, OR	Ann-Lii Cheng National Taiwan University Hospital, Taipei, Taiwan
09:40-10:10 AM	New Developments in the use of PD-1/PD-L1 Based Regimens for the Combination Immunotherapy of Cancer Jon Wigginton SITC/MacroGenics, Inc., Washington, DC	Chia-Chi(Josh) Lin National Taiwan University Hospital, Taipei, Taiwan
10:10-10:25 AM	Coffee Break	
10:25-11:10 AM	Keynote Speech: The Perspectives in Immune Modulatory Therapy of Cancer Lieping Chen CAHON/Yale Cancer Center, New Haven, CT	Yun Yen Taipei Medical University, Taipei, Taiwan
11:10-11:40 AM	CART Therapy Zihai Li CAHON/Medical University of South Carolina	Wenru Song CAHON/AstraZeneca, Gaithersburg, MD
11:40-12:10 PM	Unique Development Consideration on Cancer Immunotherapy Wenru Song CAHON/AstraZeneca, Gaithersburg, MD	James Chih-Hsin Yang National Taiwan University Hospital, Taipei, Taiwan

4th Japan Taiwan Oncology Phase I Trial Conference (JTOPIC) April 25-26, 2015

Japan Taiwan Oncology Phase I Trial Conference (JTOPIC) is intended to foster the collaboration of phase I studies between Japan and Taiwan. Key opinion leaders from academia, industry, and regulatory body are invited to cover a wide range of topics on oncology phase I trials, including the demand, the impact, and even the controversy.

Meeting Date

April 25-26 (Sat - Sun), 2015

Meeting Venue

NTUH International Convention Center (http://www.nthcc.com.tw/en/about04.htm) Auditorium 301, No. 2 Xuzhou Rd, Taipei 100, Taiwan

(25 April)Time	Topic	Speaker	Moderator
14:00-14:15 PM	Opening Remark	Ann-Lii Cheng, National Taiwan University Hospital, Taipei, Taiwan Kazuhiko Nakagawa, Kinki University, Faculty of Medicine Osaka, Japan	
14:15-14:45 PM	Keynote Speech 1: Cancer Pathology and Early Phase Trials	Yasushi Yatabe, Aichi Cancer Center, Nagoya, Japan	Teh-Ying Chou
14:45-15:00 PM	Immuno-Oncology Pipeline in AstraZeneca	Tony Ho, AstraZeneca, Gaithersburg, MD	James Chih- Hsin Yang
15:00-15:15 PM	Immuno-Oncology Pipeline in Celgene	Teng Jin Ong, Celgene, Summit, NJ	James Chih- Hsin Yang
15:15-15:30 PM	Immuno-Oncology Pipeline in Novartis	Jonathan Sun, Novartis Asia Pacific, Shanghai, China	James Chih-Hsin Yang
15:30-16:00 PM	Coffee Break		
16:00-16:30 PM	Keynote Speech 2: Breakthrough Therapy Designation	Anthony W. Tolcher, South Texas Accelerated Research Therapeutics, San Antonio, TX	Chia-Chi (Josh) Lin
16:30-16:50 PM	Recent Oncology Phase I Trials in Japan	Toshio Shimizu, Kinki University Faculty of Medicine, Osaka, Japan	Chia-Chi (Josh) Lin
16:50-17:10 PM	Recent Oncology Phase I Trials in Taiwan	Chia-Chi (Josh) Lin, National Taiwan University Hospital, Taipei, Taiwan	Kazuhiko Nakagawa
17:10-17:30 PM	3-D Cell Culture System as Platform of Drug Screening	Hironobu Minami, Kobe University Hospital, Kobe, Japan	Kazuhiko Nakagawa
17:30-17:45 PM	Current and Future Plan of Pfizer Oncology to Include Asian Countries from Early Stage Development	Tomoko Hirohashi, Pfizer Japan Inc.	Chia-Chi (Josh) Lin
17:45-17:55 PM	Wrap Up on Day One	James Chih-Hsin Yang, Department of Oncology, National Taiwan University Hospital, Taipei, Taiwan	

(26 April)Time	Topic	Speaker	Moderator
08:00-08:10 AM	Highlight on Day One	James Chih-Hsin Yang, Department of Oncology, National Taiwan University Hospital, Taipei, Taiwan	
08:10-08:30 AM	Completed Japan-Taiwan Phase I Trials: BI853520 Presenter	Toshihiko Doi, National Cancer Center Hospital East, Kashiwa, Chiba, Japan	Chia-Chi (Josh) Lin
08:30-08:50 AM	Resistance to EGFR Tyrosine Kinase Inhibitors	Kimio Yonesaka, Kinki University Faculty of Medicine, Osaka, Japan	Wu-Chou Su
08:50-09:10 AM	New Generations of EGFR Tyrosine Kinase Inhibitors	James Chih-Hsin Yang, Graduate Institute of Oncology, National Taiwan University	Wu-Chou Su
09:10-09:40 AM	Keynote Speech 3: Predictive Biomarkers of Cancer Immunotherapy	Lieping Chen, Yale Cancer Center, New Haven, CT	Yun Yen
09:40-10:10 AM	Next Generation Sequencing and Immune Repertoire	Jian Han, HudsonAlpha Institute for Biotechnology, Huntsville, AL	James Chih-Hsin Yang
10:10-10:35 AM	Coffee Break		
10:35-10:50 AM	Ongoing Early Phase Trials	Satomi Nishida, Department of Medical Oncology, Kinki University Faculty of Medicine	Chia-Chi (Josh) Lin
10:50-11:05 AM	Ongoing Early Phase Trials	Hiroaki Akamatsu, Wakayama Medical University, Wakayama, Wakayama, Japan	Chia-Chi (Josh) Lin
11:05-11:20 AM	Oncology Early Phase Pipeline in Boehringer-Ingelheim	Gerd Stehle, Boehringer- Ingelheim GmbH, Ingelheim am Rhein, Germany	Chia-Chi (Josh) Lin
11:20-11:35 AM	Oncology Early Phase Pipeline in Eisai	Akihiko Tsuruoka, Eisai Co., Ltd., Tokyo, Japan	Chia-Chi (Josh) Lin
11:35-11:50 AM	Oncology Early Phase Pipeline in Eli Lilly	Clemens Stoffregen, Eli Lilly Japan K. K., Kobe, Japan	Chia-Chi (Josh) Lin
11:50-12:05 PM	Closing Remark	Ann-Lii Cheng, National Taiwan University Hospital, Taipei, Taiwan	

三、統計中心方法介紹

JAMA 觀點-臨床試驗 Adaptive design 介紹

統計分析師 林敬峰博士

在 2012 年 6 月的美國醫學會雜誌 (The Journal of the American The Journal of the American, JAMA)中，Rieke van der Graaf 等人[1]探討研究者及參與者在進行 Adaptive design 時應考慮之事項。

Adaptive design 在臨床試驗進行中的樣本數、劑量、組別數均可改變，達到縮短藥物研發的時間。

Adaptive design 在倫理上的優點，是可以隨時檢查藥物是否有效。例如: ASTIN trial [2]原本預計收 1080 位受試者，但採用 Adaptive design 發現效果不佳後，收 966 位受試者就停止收案。

Adaptive design 有科學及倫理道德上的挑戰，此篇探討研究者及參與者皆應考慮的事項。

1. 社會跟科學價值：Adaptive design 較適合在短時間看到治療效果的 end point，對於 long-term survival 較不適合。
2. 效度：效度不易在 Adaptive design 中維持，因為隨時進行分析，故盲性和保密性無法維持，造成結果偏差。Adaptive design 也很難複製其試驗過程。
3. 受試者的選擇：Adaptive design 優點可減少受試者的傷害，因可減少受試者在效果不好的試驗組別人數。但會造成醫師阻擋病人一開始就進入研究，因較晚進入試驗對受試者較有益處。
4. 對受試者的負擔：Adaptive design 理論上受試者人數需求較少，但實際上可能會拉長試驗時間，導致樣本數增加。
5. 道德認同：Adaptive design 需要送多次 IRB。
6. 受試者同意書：

(1)受試者的同意的意願會在試驗過程中改變。

(2)如何告知受試者會使用到哪種治療方式的機率。

(3)受試者如果了解 Adaptive design 試驗後參加較有益時，會導致受試者不願意一開始就參與試驗。

References:
1. Rieke van der Graaf, Kit C. B. Roes, Johannes J. M. van Delde. Adaptive Trials in Clinical Research: Scientific and Ethical Issues to Consider. *JAMA*. 2012;307(22):2379-2380.
2. Krams M, Lees KR, Hacke W, Grieve AP, Orgogozo JM, Ford GA.ASTIN Study Investigators. Acute Stroke Therapy by Inhibition of Neutrophils (ASTIN): an adaptive dose-response study of UK-279,276 in acute ischemic stroke. Stroke. 2003;34(11):2543-2548

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