香港中文大學－新界東醫院聯網臨床研究統籌處通訊
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時間飛逝，臨床研究統籌處自2013年成立以來，在這3年間一直致力於加強管理和成為各持份者包括研究者、贊助者、支援單位、監管機構和合同研究組織之間的橋樑，以提升在新界東醫院聯網的醫院/ 診所進行的臨床研究的安全性、有效性和質素。

47個臨床研究單位由633位來自各學科的研究人員所組成；其中16個研究單位已獲得國家食品藥品監督管理總局認定。這表示我們的研究數據是獲得國家對新藥審批的承認，造福13億的中國大陸同胞。今年稍後時間將進行每三年一次的認證續期申請。在此，我衷心感謝同事們的合作，你們以高效率預備了具質素的檔案。

目前，共有691項臨床研究在臨床研究統籌處的內聯網上登記，幫助研究人員掌握他們的臨床研究狀況，而當中357項為外界資助的研究項目。作為品質改善計劃的一部份，CRMO已多次舉辦藥物臨床試驗質量管理規範（GCP）培訓班、基本心肺復甦法（BLS）工作坊、午餐研討會和線上GCP考試和進行內部視察等，確保臨床研究是符合GCP和標準操作規程（SOP）。

藥劑部（臨床研究）提供了高質素的臨床試驗藥物（IMP）管理服務，有助研究者專注於研究設計、招募受試者和進行臨床試驗。與此同時，我們亦安排了院外儲存文件和專為IST（研究者擬訂）的保險服務。

未來的數月，CRMO將會擴大服務範疇，為籌備中的臨床研究簡化行政程序。另外，革新的CRMO網站會介紹我們的卓越團隊在公私營合作的創新和早期研究中，就設計、協調、進行研究及報告的領導角式。

我們的使命是透過研究、優質護理和合作找出最好的藥物，並以此為目的。歡迎大家提出寶貴意見改善服務，努力達成共同目標。

臨床研究統籌處總監
陳重娥教授

Time flies, 3 years have passed since the CRMO was set up in 2013 to strengthen the governance and provide liaison amongst all stakeholders including investigators, sponsors, supporting units, regulatory agencies and clinical research organizations for enhancing the safety, efficacy and quality of conduct of clinical trials in the NTEC hospitals/clinics.

Amongst the 47 Clinical Research Units (CRU) comprising 633 research personnel from multiple disciplines, 16 have now received accreditation from the China Federation of Drug and Safety Administration (CFDA). This recognition has made our data available for the approval of new drugs to benefit the 1.3 billion people in Mainland China. Later on this year, we shall receive another round of inspection by the CFDA in the 3-yearly cycle for re-accreditation. Here, I wish to thank our colleagues for their cooperation in preparing the dossiers with efficiency and quality.

Currently, 691 clinical studies have been registered in the CRMO intranet which helps researchers keep track of their portfolios. Of these, 357 were externally sponsored. As part of our quality improvement programs, the CRMO has been organizing Good Clinical Practice (GCP) courses, Basic Life Support (BLS) workshops, lunch seminars and on-line GCP examination as well as conducting internal audits to ensure compliance with GCP and standard of operations (SOP).

To help our investigators focus on trial design, patient recruitment and conduct of clinical trials, the Clinical Research Pharmacy (CRP) has been providing high quality services to manage investigational medicinal products (IMP). At the same time, the CRMO has been helping investigators to arrange external archiving of trial documents and insurance for conduct of investigator-initiated clinical trials.

In the coming months, the CRMO will expand its services to streamline the administrative procedures during the preparatory phase of the clinical trials. We have revamped the CRMO website to publicize the credentials of our highly reputable clinical research teams and their leadership roles in designing, coordinating, conducting and reporting innovative and early phase studies through private public partnerships.

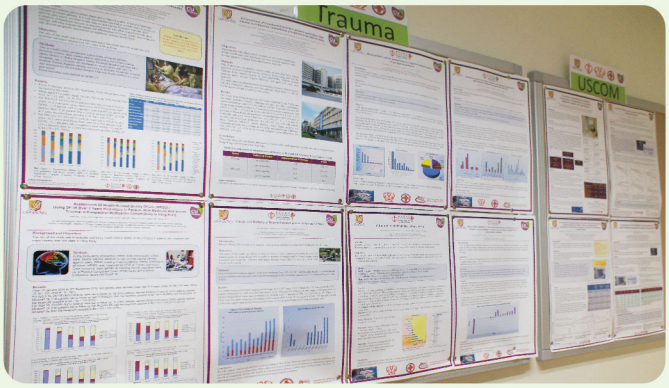
Our mission is to bring out the best of medicine through research, quality care and collaborations and to this end, we look forward to hearing from you as to how we can continue to improve our services in pursuit of this common goal.

Juliana Chan
Director
Clinical Research Management Office (CRMO)

香港中文大學意外及急救醫學教研部
Accident and Emergency Medicine Academic Unit (AEMAU) of the Chinese University of Hong Kong (CUHK)

中大意外及急救醫學教研團隊: 簡家廉教授 (右3), 洪磯正助理教授 (左3)
CUHK A&E Medicine Academic Unit: Prof. Colin A GRAHAM (Right 3), Prof. Kevin HUNG (left 3)

求診人數之多、疾病類型之廣和病人情況之緊迫，都是急症室每天的寫照；以「上戰場」形容在急症室工作的醫生，實非誇大其詞。然而，威爾斯醫院的急症室醫生，在繁重的工作和緊湊的日程中仍騰出時間參與研究，為的是改善醫療護理。目前，他們重點研究包括創傷、敗血症、痛風、鎮痛和老年醫學等五個範疇。



The large number of attendances, the vast diversity of diseases and the urgency of our patients' condition: there are the unique challenges that the Emergency Department (ED) encounters every day. It is undoubtedly appropriate to compare the ED environment to working "on the battlefield". Nevertheless, our ED colleagues endeavor to conduct clinical trials to improve the standard of care despite their heavy workload and tight schedules. Trauma, sepsis, gout, analgesia and geriatric care are their current research themes.

你們認為臨床研究是提升臨床病人護理的基石嗎？
Clinical trials are believed to be the cornerstone of improvements in clinical care. What do you think?

Graham教授，洪教授：

臨床研究對推動改善臨床護理的重要性是肯定的。我們最近所發表的論文，被廣泛視為臨床實踐上的改變，並為急症服務提供了敗血症復甦及處理急性痛風性關節炎的重要臨床答案。

在2014年發表在新英格蘭醫學雜誌（New England Journal of Medicine）的Australasian Resuscitation in Sepsis Evaluation（ARISE）論文，調查早期目標導向治療（EGDT）對早期敗血性休克病者的多中心臨床研究，我們成為招募香港研究對象的協調中心之一。病人按隨機被分配進行EGDT或常規護理，結果顯示，對於早期敗血性休克的垂危病者，EGDT並不能減低90日的全因死亡率；[1] 這結果影響了隨後敗血症管理的主要國際準則。

Prof. Graham & Prof. Hung:

Clinical trials are definitely important to drive the improvement of clinical care. We have recently published papers reporting clinical trials that were widely regarded as practice changing, and provided answers to important clinical problems in sepsis resuscitation and the management of acute gouty arthritis in the ED.

In 2014 the Australasian Resuscitation in Sepsis Evaluation (ARISE) trial was published in the New England Journal of Medicine. We were one of the coordinators for Hong Kong recruitment in this multi-center study to investigate early goal-directed resuscitation (EGDT) for patients with early septic shock. The patients were randomly assigned to receive either EGDT or usual care. The results showed that EGDT did not reduce the 90-day all-cause mortality

另一項是急性痛風症管理，非類固醇消炎藥物(NASIDs) 如Indomethacin是治療急性痛風症的一線治療藥物，但不適用於長者、腎功能不全和腸胃病患者。鑑於口服皮質醇潑尼松龍（Prednisolone）的安全和有效性，在我們一項隨機、雙盲對照的多中心臨床研究，顯示Prednisolone可被考慮成為不適用於NASIDs病患者的代替方案。[2] 這些例子還凸顯了一個事實，縱然我們常常得不到藥廠的贊助，但我們仍樂於進行對病人有利的臨床研究。

以上兩個例子均指出，臨床研究是改善病人護理和影響醫療體系的重要一環。

威爾斯親王醫院創傷中心內設備完善的創傷及急救室
The well-equipped trauma and resuscitation room at PWH trauma centre.

of the critically ill patient with early septic shock.[1] This has impacted the recommendations in the subsequent major international guidelines on sepsis management.

Acute gout management is another research theme. Anti-inflammatory drugs (NSAIDs) such as indomethacin were recommended as the first-line agents. However, they are not suitable for elderly patients and patients with renal insufficiency or gastrointestinal disease. In the light of the safety and effectiveness of the oral corticosteroid prednisolone, our double-blind, randomized, controlled multi-center trial showed that prednisolone could be considered as a first-line alternative for patient who is not suitable to take NSAID.[2] These examples also highlighted the fact that often our trials are without pharmaceutical sponsorship, but worthwhile to conduct for its beneficial impact on our patients.

These two examples point out that clinical trials are the key to improve medical care and makes an impact on the medical system.

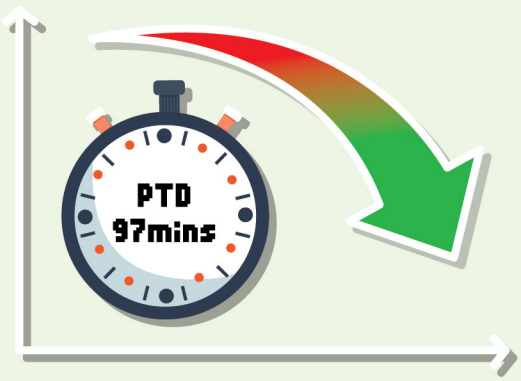
談談你們的重點研究範疇？
What are your focus areas?

Graham教授，洪教授：

除了敗血症護理和急性痛風性關節炎外，對嚴重創傷患者的復甦是另一項重點研究。

香港五個創傷中心是根據 Donald Trunkey 教授於1994年呈交醫管局報告中的建議而成立的。在初段創傷分流（PTD）實施前，嚴重創傷病人會送到就近醫院搶救，待病人情況穩定後，就轉送到創傷中心作進一步評估和介入治療。

威爾斯醫院和新界東醫院聯網是本港首個進行初段創傷分流（PTD）的試點。我們與消防處和雅麗氏何妙齡那打素醫院合作，讓嚴重創傷病人免除醫院間轉介而直接送往創傷中心，這項前瞻性研究顯示，創傷病人透過 PTD 可提早97分鐘得到妥切的治療。[3]



Prof. Graham & Prof. Hung:

Apart from our work in sepsis care and acute gouty arthritis, research on resuscitation of major trauma patients is another major focus.

Designation of 5 trauma centers were based on the recommendation outlined by Prof. Donald Trunkey in his report to the Hospital Authority in 1994. Before the implementation of primary trauma diversion (PTD), major trauma patients had been transported to the nearest hospital for resuscitation and then transferred to trauma center after initial stabilization for further evaluation and intervention.

PWH and the New Territories East Cluster was the first to pilot the feasibility of PTD in Hong Kong. We collaborated with the Fire Service Department and Alice Ho Mui Ling Nethersole Hospital (AHNH) to see if major trauma patients could benefit from direct transportation to the trauma center rather than inter-hospital transfer. Our prospective study showed that trauma patients could reach definitive care 97 minutes earlier by using PTD. [3]

在威爾斯醫院進行意外及急救醫學 (A&E) 研究有什麼優勢？
What are the research strengths of Accident & Emergency Medicine (A&E) in PWH?

Graham教授，洪教授：

香港是人口密集的城市，每日到威爾斯醫院急症室求診的病人平均約400人，大量求診人數對招收病人進行臨床研究，無疑是提供了有利條件；還有，我們的同事經常與院內各部門有緊密的合作，這都是我們進行臨床研究的優越之處。

每日到威爾斯醫院急症室求診的病人平均約400人
Average daily attendance of PWH ED is around 400 patients.

Prof. Graham & Prof. Hung:

Hong Kong is a densely populated city; the average daily attendance of PWH ED is around 400 patients. The large number of daily attendance is definitely beneficial for subject recruitment. In addition, our department collaborates frequently with the rest of departments within the hospital. These are our strengths in conducting clinical study.

你們可否給予一些有利A&E臨床試驗的建議？
Can you give some suggestions to make the clinical trial of A&E much more favorable?

Graham教授， 洪教授：

政府資助對推動臨床研究扮演著重要角式；彼鄰新加坡的急症醫學研究，隨著政府的支持而躍進一大步。反觀香港，雖然急症醫學在1997年已成為香港醫學專科學院其中一門專科，但並未納入申請政府的優配研究金（GRF）的專門類別，這方面實在有需要改善。

對於A&E研究，獲取病人知情同意書的程序亦是值得討論和可改善的；在面對生與死的瞬息之間，以慣常程序向垂危病人或陪同家屬獲取病人知情同意，並不可行。在澳洲，政府透過不同的媒體教育市民，關於創傷護理臨床研究對象的招募和「選擇退出」的政策；一旦市民遭遇嚴重創傷而不表示「選擇退出」時，即自動成為研究對象。這政策是經過各方詳細的諮詢和嚴格的管理，確保病危者的安全和權益得到保障，同時亦得到公眾廣泛的接受。

如果政府能在研究資助政策上配合、獲取病人知情同意上能更靈活的安排，我們就能抓緊病人數目眾多的機遇，進行更多的循證研究。

Prof. Graham & Prof. Hung:

Government funding plays an important role in driving clinical trials. With the inclination of government support, research in emergency medicine in Singapore has taken a great leap. In contrast, emergency medicine research is not one of the categories in General Research Fund (GRF), even though emergency medicine has been one of the specialties under the Hong Kong Academy of Medicine since 1997. Improvement in funding is required.

Discussion and improvement for informed consent process is urged especially for A&E. Hovering between life and death, it is often impossible to obtain the informed consent from the critically ill patient or their accompanying family members using routine procedures. In Australia, the government has educated their residents through different media about the recruitment of subjects for clinical trials in trauma care. Residents could be recruited as research subject automatically when they suffer from major trauma and an 'opting out' policy is used. This policy is accompanied by detailed consultation with relevant parties, and stringent governance in the implementation which allows broad public acceptance in conducting clinical trials for patients in critical conditions, whilst protecting the safety and rights of patients.

More evidence-based research can be conducted if we can seize the opportunity of high attendance, appropriate funding policy together with more effective arrangement in obtaining the informed consent.

展望將來
What are your targets?

Graham教授，洪教授：

與世界其他已發展的國家比較，香港的急救護理仍有一些重點領域是有待改進的。在西雅圖，院外心臟驟停的急救成功率是40%；而香港在過去20年一直維持在1%左右。

此外，我們比對澳洲維多利亞省與香港嚴重創傷病人其功能復康的結果，經調整關鍵性的混雜因素後，顯示兩地的病人在康復後6個月和12個月的功能結果，並無差異；[4] 然而，我們的研究結果亦顯示，香港康復者回到職場工作的比率是低於澳洲和荷蘭。

對病人來說，「活著」與「活得好」是截然不同的兩回事；為幫助病人活得好，我們著手連繫整個醫療系統：包括教育、院前護理（如初段創傷分流）、住院期間的診斷和治療、和出院後的跟進（如物理治療、心理健康跟進等）。若每一環節緊扣並適時進行，病人的康復將會明顯的提升。我們期待與更多不同部門和團體有更緊密的合作，為創傷病人提供更優質護理。

Prof. Graham & Prof. Hung:

Hong Kong has some key areas for improvement in terms of emergency care compared with other developed countries in the world. In Seattle, the successful rate in resuscitation of out of hospital cardiac arrest is 40%, compared with the rate of Hong Kong is around 1% in the past 20 years.

Furthermore, the longer term recovery of emergency conditions are important to us. In comparing the functional outcome of major trauma patient between State of Victoria, Australia and Hong Kong, our study showed similar outcomes in 6 and 12 months after adjusting for key confounders.[4] However, our results showed that the rate of return to work is low in Hong Kong compared with Australia and the Netherlands.

"Survive" and "survive well" are totally different to patient. To help our patient to 'survive well', we have to set linkage between the whole system of medical care. Whole system including education, pre-hospital care (e.g., PTD), in-hospital diagnosis and treatment, and post-hospital follow-up (e.g., physical rehabilitation, psychological follow-up). If every steps can be done at the right time, our patient will be impacted with significant improvement. We look forward to having more and closer collaboration with different disciplines and the community to provide better care for our patients.

Reference:
1. ARISE Investigators; ANZICS Clinical Trials Group, Peake SL et al. *N Engl J Med*. 2014; 371(16):1496-506.
2. Rainer TH et al. *Ann Intern Med*. 2016; 164(7):464-71.
3. Cheung NK et al. *J Trauma*. 2006; 61(4):954-60.
4. Rainer TH et al. *PloS One*. 2014; 9(8).

每日提要 Tips of the day

管理生物樣品的一般性原則是什麼？
What are the general principles of biological sample management?

處理生物樣本的整個過程，包括但不限於標記、收集、處理、儲存和運送等程序，必須要清楚記錄及可追溯的。為了有妥善的文件記錄，新的儲存生物樣本區域圖(例如：電冰箱)和生物樣本記錄的範本，已更新在CRMO-SOP-020。此外，工作區域必須保持清潔，設備亦要維持在可靠及性能良好的狀態。

Entire handling processes of biological specimen including but not limited to labelling, collection, processing, storage, and transferring must be documented clearly and be traceable. For proper documentation, new mapping template for the storage area of biological samples (e.g., freezer) and biological sample log template have been included in the new version of CRMO-SOP-020. In addition, working area must be clean and the equipment(s) must be maintained in reliable and functional condition.

如何處理不再需要保留的研究文檔？
How to handle the study document if it is no longer needed to be retained?

對於公司贊助的研究，當與研究相關的文件毋須再保留時，申辦者有責任以書面形式通知研究者/ 機構（ICH-GCP 4.9.5, 5.5.12）；研究者亦可按臨床試驗協議書內的具體要求去處理研究文檔。

至於研究者申辦的研究，研究者應採取適當的措施銷毀文件檔，防止敏感資料外洩；而碎紙公司所提供的文件銷毀服務是可行的解決方法之一。

For the company-sponsored study, sponsor is responsible to inform the investigator/ institution in writing when the trial related documents are no longer needed to be retained (ICH-GCP 4.9.5, 5.5.12). Investigator can also refer to the clinical trial agreement if there are any specific handling requirement(s) on the study documents.

For the investigator-sponsored study, investigator should destroy the documents with proper measures to prevent leaks of the sensitive documents. Secure shredding offered by shredding service company is one of the possible solution.

若研究者擬定的臨床研究（IST）獲藥廠財政贊助，誰是該研究的「申辦者」？
If drug company provide financial sponsorship to an investigator-sponsored trial (IST), who will be the “Sponsor” of that trail?

「申辦者」不僅是提供財政資助，還要承擔廣泛的責任，包括但不限於科學、管理、監管、法律和財務責任；研究所得的數據、結果和知識產權等皆由申辦者所擁有。

若藥廠只是財政的贊助，並沒有賠償和保險提供，而所有的責任均由IST的研究者承擔，則「申辦者」是IST本人；有關的知識產權，研究者有權決定是否與藥廠分享數據。

“Sponsor” not only provide financial sponsorship, it also embodies a broad range of responsibilities including but not limited to scientific, management, regulatory, legal and financial responsibilities. The data, results and intellectual property rights derived from the studies are owned by the sponsor.

The mentioned study is an IST as the company only funds the investigator. No indemnity and insurance is provided by the company and all other liabilities rests on the investigator. For the intellectual property, investigator has the right to decide whether he would like to share the data with the company.

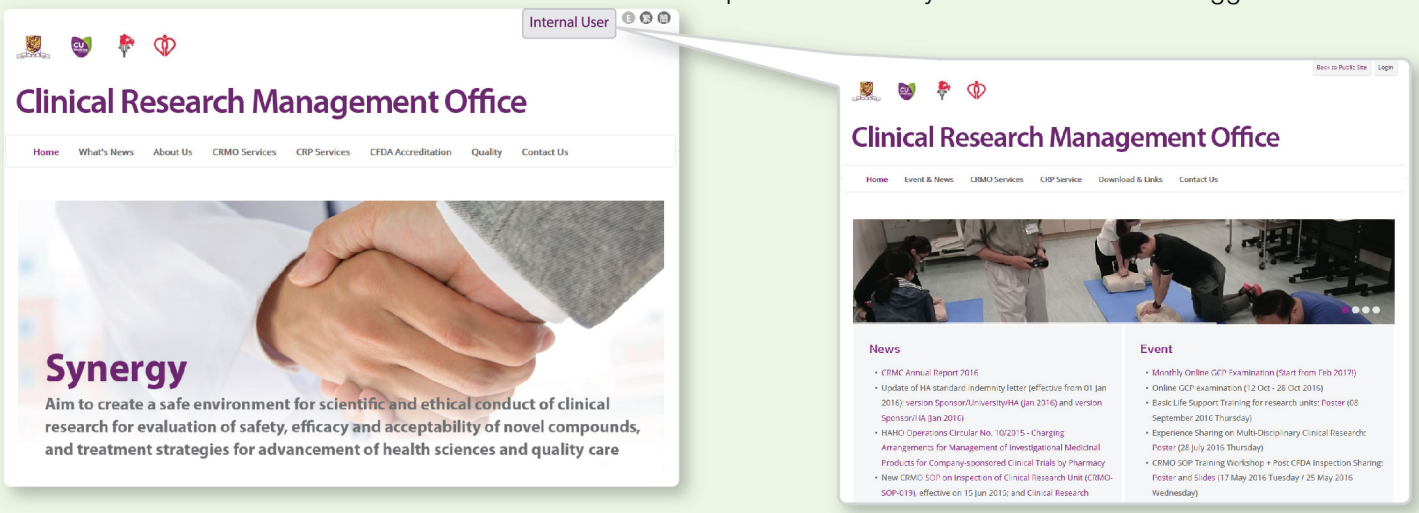
通告 Announcement

全新CRMO網站 www.crmo.med.cuhk.edu.hk

全新的CRMO網站已經推出！這設計清晰易用及備有不同服務對象的特定功能選單。主頁是向公眾簡介CRMO和我們的研究團隊。至於中文大學/ 新界東醫院聯網的同事，按「內部用戶」即能獲得更具體的資訊如：快將舉辦的工作坊等。歡迎大家就網頁提出意見和提議。

New CRMO website www.crmo.med.cuhk.edu.hk

Our brand new website is launched! The new design allows for tailored menus, clear and easy navigation, and a responsive layout. The home page introduces CRMO and the credentials of our research teams for the public. For our CUHK/ NTEC colleagues, you can click "Internal User" to get more specific information e.g., upcoming workshop that matter you. Please feel free to provide us with your comments and suggestion.



每月GCP線上測驗

為滿足同事的需求，我們進一步提升服務，定期在每月的首十天舉行 GCP 線上測驗，歡迎CRMO網站的登記會員或非會員參加考試。非登記會員可隨時註冊 (全年接受) 後參加測驗。有關參加和簽發證書的詳情，請瀏覽 http://intranet.crmo.med.cuhk.edu.hk/en-us/crmoservices/onlinetest.aspx#ot.

Launch of monthly GCP online test

The online GCP test is launched routinely at the first 10 calendar days of every month and the registration is open all year round. Both CRMO website registered member and non-registered member are welcomed to take the test. For details of participation and issue of certificate, please visit our website http://intranet.crmo.med.cuhk.edu.hk/en-us/crmoservices/onlinetest.aspx#ot .

更新臨床試驗保險申請表和修改表

已更新的臨床試驗保險申請表和修改表在2017年1月1日正式生效，當中增加了必要文件檢查清單以供校核。有意購買臨床試驗保險的首席研究者，應在臨床研究開始前，向臨床研究統籌處提交最新的倫理委員會批准書和試驗方案以作申請。

當有任何修改，如更改首席研究者/ 協調研究者、研究受試者數目、修訂試驗方案，請及早聯絡臨床研究統籌處。如有任何疑問，歡迎查詢，又或瀏覽本處網頁 http://intranet.crmo.med.cuhk.edu.hk/en-us/crmoservices/clinicaltrialinsurance.aspx#ot .

Change of application form and amendment form for clinical trial insurance

The Clinical Trial Insurance application form and amendment form have been updated with effective on 1 Jan 2017. A checklist of essential documents has been added for checking. PI should approach CRMO together with the updated ethics approval and a study protocol for application before commencement of the trial.

If there is any amendment, e.g., change of PI/ Co-I, study subject number, protocol amendment, please inform CRMO by using the amendment form in timely manner. Please feel free to contact us for further enquiry or you can visit our website for details http://intranet.crmo.med.cuhk.edu.hk/en-us/crmoservices/clinicaltrialinsurance.aspx#ot.

工作坊 Workshops

ICH-GCP一天工作坊

為同事舉辦的GCP一天工作坊已於3月4日順利完成；是次培訓得到 Trancelerate Biopharma 認可及全球不同藥廠研究申辦者所接受。另外，我們亦在3月18日為從事中醫藥臨床試驗的同事，安排了半天GCP工作坊（中文大學中西醫結合醫務中心協辦）。兩個工作坊均由經驗豐富的專業人士指導，並且得到熱烈的建設性回應。

One-Day ICH-GCP Workshop

A one-day GCP workshop was held on 4 Mar for our colleagues. The training was recognized by Trancelerate Biopharma and would be accepted globally by pharmaceutical companies. Additionally, a half-day Chinese workshop on GCP (co-organized with the Institute of Integrated Medicine) was arranged on 18 Mar for our colleagues who conduct clinical trials with Traditional Chinese Medicine. Instructed by seasoned professionals, both workshops received raved responses with constructive exchanges.

臨床研究視察分享工作坊

聚焦於臨床研究視察的午間工作坊已於3月27日舉行；當日CRMO與百多位來自不同部門的研究同事，分享常見的視察結果。其間還簡介了協助研究者的CRMO新服務，有關服務詳情將會於稍後時間向中大同事發送。

Sharing Session on Clinical Research Inspections

A one-hour workshop focusing clinical research inspection was held on 27 Mar. The workshop allowed CRMO to share the common inspection findings with over 100 research staffs working in different departments. Additional CRMO services intended to assist our investigators were also introduced during the workshop. More information on the new CRMO services will be sent to our CUHK colleagues once available.

聯絡方法 Contact us

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