Joint CUHK-NTEC CRMO Newsletter

Issue 4: Oct 2015

Director's Message

The mission of Clinical Research Management Committee (CRMC) is to improve the safety of research subjects, the integrity of research conduct and the compliance of regulatory requirements in accordance to Good Clinical Practice (GCP).

In order to ensure compliance of our clinical research activities with the protocol, CUHK-NTEC CRMO SOPs, ICH-GCP and relevant regulatory requirement, a Clinical Research Inspection Team is set up to conduct regular, independent and systematic inspections on our Clinical Research Units. The Clinical Research Inspection Team is composed of experienced clinical research colleagues from CRMO, CREC and the current CFDA-accredited units.

We would like to express our gratitude to these colleagues who are willing to share their experience with other colleagues. Through the interactive collaboration and exchange, we can all learn and grow together for the compliance of clinical research.

Name	Dept/ Division
Prof. Juliana CHAN	CRMO
Ms. Iris CHAN	CRMO
Dr. Benny FOK	CRMO
Dr. Simon CHAN	CREC
Ms. Envy LEE	CREC
Ms. Jenny NG	CREC
Ms. Evelyn CHAU	BABE
Ms. Olivia TO	Cardiology
Dr. Risa OZAKI	Endocrinology
Ms. Cherry CHIU	Endocrinology
Ms. Jessica CHING	GI
Ms. Angel CHIM	GI
Dr. Edwin HUI	Oncology
Dr. Vincent LEE	Paediatrics

Events

Clinical Research Financial Management Workshop

A luncheon workshop on financial management of clinical research was held on 14th Jul, 2015. Perspective from study sponsor as well as experience from study site on study budget development was shared with 100 clinical research colleagues of different departments. The speakers demonstrated how a study budget should be developed and emphasized that all study-related procedures should be accounted for in the study budget. Apart from the study visits, study budgets should also include study preparation, document archival, and other relevant administrative costs. Nevertheless, the budget proposed should be reasonable and justifiable. With the encouraging feedbacks and constructive comments received, a second workshop on study budget will be arranged in early 2016. More information will be sent to our colleagues via email later.

CREC and CRMO Workshop on Clinical Trial

CREC and CRMO jointly conducted a workshop on 26th Jun 2015 to get our clinical research colleagues familiar with the application of ethics committee approval and hospital approval. Requirements and the keys for the application were shared with our attendees so that the approval process can be more efficient. For details, please refer to the slides uploaded on the CRMC website (Under CRMO Service/ Seminars and Workshops).

Feature Article

The Division of Neurology of the Department of Medicine and Therapeutics has emerged to be an excellent center of clinical trial in fields of stroke, dementia and multiple sclerosis. We are glad to invite four neurologists to share their missions and foresights.

Working on stroke for one-fourth century

Prof. Lawrence WONG Ka-sing
Professor of Department of Medicine and Therapeutics; Chief of the Division of Neurology;
Director of the S.H. Ho Cardiovascular Disease & Stroke Center

Narrowing of carotid artery was commonly believed worldwide as the cause of ischaemic stroke. Prof. Wong Ka-sing is the first to prove that the intracranial atherosclerosis (ICAS) is the prevalent cause of stroke in Chinese population, and his finding recasts the understanding about the cause of stroke especially for the Asian population. He also changes the management guideline of stroke adopted by the Western using double anti-platelet therapy to reduce the microembolus aggregation and hence lower the rate of stroke recurrence.

His groundbreaking findings not only benefit the stroke patient, but also give a bounce to the local stroke research with various supports from University Grant Committee (UGC), sponsorship and international collaboration.

To predict subsequent risk of stroke recurrence, Prof. Wong, in partnership with computer scientist, conducted a study about hemodynamic characteristic of ICAS using computational fluid dynamics (CFD) models (*PloS One*. 2014; 9(5)). He aims at finding an index to direct appropriate and aggressive management for high-risk stroke patients.

Prof. Wong has also been targeting the early stage rehabilitation therapy after stroke by using robotic arm rehabilitation, transcranial magnetic stimulation, and blood flow augmentation.

For those engaging in stroke research, Prof. Wong says “It is a tough battle to commit yourself in research without taking pleasure in the course of inquiry. Stay curious! Stay enthusiasm! These are the keys to win the battle”.

Dream of Mine, Dream of Dementia Patient

Prof. Vincent Mok Chung-tong
Assistant Dean (Admission); Professor of Department of Medicine and Therapeutics

“I have a dream! That cognitive impairment among the elderly can be prevented. At least, its onset can be delayed”, says Prof. Vincent Mok Chung-tong.

Prof. Mok is the pioneer in Asia, devoted in studying the relationship between cerebral small vessel disease and cognitive impairment (VCI). “Ten years ago, this area was left unattended especially among Asians”, says Prof. Mok.

With the support from grants, donations and patients’ participation, many of his studies, including reviews, relating to association between stroke and cognitive impairment, mechanisms of how small vessel disease induces cognitive decline, and clinical trials on VCI, have been published in high impact journals, like *Nature Review Neurology, Alzheimer’s & Dement, J Neurol Neurosurg Psychiatry and Stroke*.

Furthermore, since cognitive tests used for Alzheimer’s dementia are not sensitive for evaluation of VCI, Prof. Mok, along with Dr Adrian Wong (Research Assistant Professor) have developed tailored-VCI test batteries to accurately assess severity of cognitive impairment for the Chinese population (*J Neurol Neurosurg Psychiatry* 2013; 84: 499-504).

“It is almost impossible to bring dead neurons back to life. It is therefore too late to treat patients when dementia already sets in, when significant neuronal damage has already happened. At present, with the support from 2 GRF grants, we are working on the early detection of dementia-free subjects who are at risk for developing VCI and we are currently conducting one of the first clinical trials in the world in evaluating effectiveness of a drug for the primary prevention of VCI in high risk subjects. Our desire is to prevent dementia from afflicting elderly individuals ”, says Prof. Mok.

Feature Article

Leading the trend of stroke research

Dr. Thomas LEUNG Wai-hong
Lee Quo Wei Associate Professor of Neurology (Chief of Acute Stroke Unit)

Dr. Thomas Leung Wai-hong dedicates to unmask the predisposition of the stroke development using various non-invasive imaging tools, such as transcranial Doppler ultrasound, MRI, CT, and 3D angiography. He works closely with international collaborators to reveal the genetic background of intracranial stenosis in order to further understand the development of this disease in Asian population. Based on patient's genetic makeup, Dr. Leung aims at developing personalized medicine to predict the risk and customize therapy. In addition, he has been studying the interventional treatment by implanting stent to support obstructed blood vessel and using ischemic stroke system (ISS) to augment the cerebral blood flow.

Dr. Leung never stops in improving stroke diagnosis and treatment. He has collaborated with the Department of Health Technology and Informatics at Hong Kong Polytechnic University (PolyU) in developing a unique Telestroke system using smartphone to facilitate the neurologist to conduct distant assessment for thrombolysis outside clinical hours. This system helps relieving the manpower limitation of neurologists and improves the healthcare service for stroke patients. In view of the innovation, HIMSS-Elsevier Digital Healthcare Award 2013 was granted to this Telestroke system.

For the forthcoming challenge, he hopes more promotion can be launched to encourage patients to join the clinical research. "Patient's contribution on research exerts leverage on the understanding of the disease and therapy development. Without their participation, we only had little understanding about stroke", says Dr. Leung.

Young researcher. New adventure

Dr. Alexander LAU Yuk-lun
Assistant Professor of Department of Medicine and Therapeutics
Deputy Chief Clinician of Integrative Medical Centre of Hong Kong Institute of Integrative Medicine

Dedicating in uncharted research area is full of challenges. Dr. Alexander Lau Yuk-lun, a former student of Professor Lawrence Wong, determines to establish his niche in multiple sclerosis (MS) research.

In 2012, Dr. Lau set up a large scale registry for Hong Kong MS patients. "It is a new page to Hong Kong MS patients as they are left unattended in Hong Kong for years", says Dr. Lau. This registry not only further his understanding about MS and related disorders, but also lays solid foundation for local MS research. His effort was well recognized by Hong Kong College of Physicians and was granted with Young Investigator Grant in 2012. With the support from Health and Medical Research Fund (HMRF), Dr. Lau has been carrying a multi-center study with the Immunology laboratory of Queen Mary Hospital and 10 other local hospitals to evaluate neutralizing antibody of MS patients using interferon. Furthermore, Dr. Lau is working closely with Dr. Jill Abrigo of Department of Imaging and Interventional Radiology to develop a standardized MRI protocol for MS patients to have a more comprehensive disease monitoring and development of novel biomarkers.

In addition to conventional therapy, Dr. Lau is working with Dr. William Cheung Hiu-ngai at the Integrative Medical Centre of Hong Kong Institute of Integrative Medicine on integrative treatment using Chinese medicine. In his pilot study, his team finds that the relationship between fatigue and deficiency of Qi (氣虛) in the early stage of recurrent MS is high. In the next step, he will develop an interventional trial using acupuncture to treat the MS.

Announcements

Partnership with Pfizer (INSPIRE site)

The Chinese University of Hong Kong/ Prince of Wales Hospital has been selected as a site of INSPIRE (Investigator Networks, Site Partnerships and Infrastructure for Research Excellence) by Pfizer in Apr 2015, which indicates a recognition of our research capability and performance.


Pfizer

INSPIRE Sites

Certificate of Approval

This is to certify that

The Chinese University of Hong Kong, Prince of Wales Hospital

Has been selected as

INSPIRE site

(Investigator Networks, Site Partnerships and Infrastructure for Research Excellence)

As of

01st April 2015

Molly Chen
Investigator Site Development Lead

*The certificate is valid for 1 year from the date of approval

New arrangement for the application for the Clinical Trial Insurance

With effective from Jul 2015, a new insurance company (Newline Asia Services Pte. Ltd.) for clinical trial insurance has been used. For the details of the coverage, please refer to the website of Bursary. Application of clinical trial insurance can be arranged via CRMO.

Tips of the Day

Q1: Is there any guideline about the disposal of clinical waste of study subject?

For the disposal of clinical waste generated in connection with clinical practice and researches, you may refer to the Clinical Waste Management Plan (CWMP) which is based on the CAP 354O - Waste Disposal (Clinical Waste) (General) regulation. Details can be referred to HAHO Operation Circular No.5/2012 which can be downloaded from CRMC website (Under SOP/ HA NTEC SOPs related to clinical research). ✓✓

Q2: A CRP undertaking is needed for hospital approval of a drug study in PWH. What is a CRP undertaking and how this is arranged?

The Clinical Research Pharmacy (CRP) has been set up in Apr 2015 to ensure safe and quality management of study drugs. When a drug study is planned, the Principal Investigator (PI) of PWH should contact CRP to discuss about logistic arrangement of study drug(s). An undertaking will be signed by CRP and PI upon reaching an agreement. This is only applicable for drug study conducted in PWH. Afterward please attach a copy of the duly signed undertaking when you apply for hospital approval of the study. ✓✓

Q3: Why the study visit shall be input to HA CMS?

Investigators should enter information about study subject into HA CMS so that other clinical teams (either within the same hospital or in other hospitals) are aware of patients' participation in the trial when managing patients. This can also avoid duplicated inclusion of a patient to 2 studies.

Essential information including study short title/ protocol number/ CREC number, name of PI and contact telephone number should be outlined in CMS Alert, and more details can be included in the CMS Reminder. The progress of the patient can be recorded in the Consultation Note. The medication profile of the patient should also be updated. ✓✓

Upcoming Events

One-day ICH-GCP Workshop

An one day GCP workshop will be organized again this year on 7th Nov. This training will be conducted by seasoned speakers who have comprehensive experience in ICH-GCP, it is identified by TransCelerate BioPharma and hence recognized by various global study sponsors. Colleagues of CUHK and NTEC hospitals who have less than 2 years of experience in clinical research or who would like to learn more about ICH-GCP are welcomed to join this workshop. You can get more details about the workshop and register for the workshop on CRMC website http://www.crmc.med.cuhk.edu.hk/Whatsnew/EventsandTrainings.aspx.

Clinical Trial Planning Workshop for Investigator Sponsored Trials (IST)

A series of luncheon workshops will be organized by the CRMO focusing on various aspects related to investigator sponsored trials. Topics of these workshops would include: research grant application, protocol development, budget development, and clinical study oversight. These workshops are intended for colleagues of CUHK and the NTEC hospitals who are interested in conducting academic clinical studies. The first workshop will be held on 9th Dec focusing on the procedures involved in research grant applications, ethics and regulatory applications and insurance policies. More details will be sent via email.

Contact us

Joint CUHK-NTEC Clinical Research Management Office (CRMO)

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Website: *http://www.crmc.med.cuhk.edu.hk* E-mail: *crmo@cuhk.edu.hk* Tel: (852) 2632 4276

香港中文大學－新界東醫院聯網臨床研究統籌處通訊

第四期：2015年10月

處長的話

臨床研究管理委員會(CRMC)的使命是提高臨床研究對象的安全性和研究管理的完整性，以符合藥物臨床試驗質量管理規範(GCP)的必要相關條件。

為了確保我們的臨床研究活動能遵從臨床試驗方案、中文大學－新界東醫院聯網臨床研究統籌處的標準操作規程(CRMO-SOPs)、國際協調會議－藥物臨床試驗質量管理規範(ICH-GCP)和相關法規，我們成立了臨床研究視察團隊，進行常規、獨立和系統化的視察。團隊的成員來自臨床研究統籌處(CRMO)、臨床研究倫理聯席委員會(CREC)和現時已獲得國家食品藥品監督管理總局(CFDA)認證的研究單位內具豐富臨床研究經驗的同事。

我們非常感激團隊內的同事樂意與其他同事分享他們的經驗；透過互動協作與交流，我們定能共同學習與成長。

成員姓名	部門專科 / 專科
陳重娥教授	臨床研究統籌處 (CRMO)
陳虹小姐	臨床研究統籌處 (CRMO)
霍兆邦博士	臨床研究統籌處 (CRMO)
陳建昌醫生	臨床研究倫理聯席委員會 (CREC)
李秀芳小姐	臨床研究倫理聯席委員會 (CREC)
吳碧詩小姐	臨床研究倫理聯席委員會 (CREC)
周綺雯小姐	生物等效性試驗 (BABE)
杜紫菱小姐	心血管 (Cardiology)
尾崎麗莎醫生	內分泌 (Endocrinology)
趙潔平小姐	內分泌 (Endocrinology)
程月玲小姐	消化 (GI)
詹美玲小姐	消化 (GI)
許斌醫生	腫瘤 (Oncology)
李偉生醫生	兒科 (Paediatrics)

活動剪影

臨床研究財務管理工作坊

臨床研究財務管理午間工作坊已於2015年7月14日舉行。我們向一百位不同部門的臨床研究同事作出分享，分別從研究申辦者和研究者的角度，解釋如何建立臨床研究的財政預算。講員們示範如何建立研究預算案，並強調所有與研究相關的程序都要計算在研究經費內。除了研究隨訪，預算還需要包括前期預備、文件存檔和其他相關的行政費用。當然，提出的預算費用必須合理。因著大家所提出建設性的建議和令人鼓舞的回應，第二個財務管理工作坊將於2016年初舉辦，詳情將於日後透過電郵發佈。

CREC和CRMO審批臨床研究准許工作坊

CREC與CRMO在2015年6月26日合辦了一場工作坊，幫助臨床研究的同事認識申請CREC臨床研究道德倫理及醫院對臨床研究的批准程序，特別強調解說相關申請的關鍵和要求，使申請過程更為順暢。該工作坊的資料可於CRMC網頁下載 (臨床研究統籌處服務範疇/ 研討會與工作坊)。

卓越團隊掠影

威爾斯親王醫院香港中文大學內科及藥物治療學系的腦神經科，在中風、失智症及多發性硬化症的臨床研究領域中，是眾所周知的卓越中心。我們邀請了四位腦神經專科醫生，分享他們的使命和願景。

致力中風研究四分一世紀

黃家星教授

內科及藥物治療學系教授；腦神經科主任；何善衡心腦血管病中心所長

全球各地曾經相信頸動脈狹窄是引致缺血性中風的元凶。黃家星教授是首位證實顱內動脈粥樣硬化(ICAS)是導致中國人罹患中風的主要因素；這發現重塑對中風成因－特別於亞洲人－的理解。黃教授也改變了過往採用西方模式對預防中風的指引；他使用雙重抗血小板療法減低微栓子凝結，藉此減低中風的復發。

他的開創性發現不只造福中風病人；更帶來大學教育資助委員會(UGC)研究經費和贊助、國際間各方面的支持及共同合作，促進本地中風研究蓬勃發展。

為了預測中風復發的風險，黃教授與計算機科學家合作，他們利用計算流體動力學(CFD)模型，進行顱內動脈粥樣硬化(ICAS)的血液動力學特徵研究(*PloS One.* 2014;9(5))，為高危病人制定指標，提供合適和進取的治療方案。

黃教授也專注於中風的早期復康療法，他利用機械手、經顱磁刺激和透過機器增加腦部血流量治療以助病者康復。

作為中風領域的先行者，黃教授勉勵一眾年輕的研究者：「投身研究無疑是一場艱苦的戰役；保持好奇心！持守熱誠！享受當中尋索過程的樂趣！這都是致勝的秘訣。」

我的夢－失智症患者的夢

莫仲棠教授

醫學院助理院長(入學組)；內科及藥物治療學系教授

「讓老年人的認知障礙成為能預防的疾病是我的夢想！至少，它的發病能被延遲。」莫仲棠教授說。

莫教授是亞洲區的先鋒，他致力投身於研究腦小血管病變與認知障礙(VCI)的相互關係。「十多年前，這一領域在亞洲是未被注意的。」他說。

莫教授的卓越研究有賴各方的研究資助、捐款和病人的參與。很多他的研究，包括有關中風與認知障礙的聯系、腦小血管病變導致認知能力下降的機制的文獻評論和認知障礙的臨床試驗等，都已發表在具影響力的科學期刊，如*Nature Review Neurology, Alzheimer's & Dement, J Neurol Neurosurg Psychiatry and Stroke*。

再者，沿用於阿滋海默氏痴呆症的認知測試，用以評估VCI的敏感度不足；莫教授與黃沛霖博士(研究助理教授)共同合作，為中國人制訂出一系列測試，準確地量度VCI的嚴重程度(*J Neurol Neurosurg Phsychiatry* 2013; 84: 499-504)。

「要已死的神經復生，幾乎是不可能的事。當病人出現痴呆徵狀、或重大的神經創傷時，即使治療也是太遲。目前，我們得到兩個優配研究基金的資助，為有潛在VCI風險的精靈長者做早期檢測；與此同時，我們正進行全球首個臨床試驗，評估藥物對VCI高風險人士的預防效用。我們的心願是長者免受痴呆症的折磨。」莫教授道出心聲。

卓越團隊掠影

開拓中風研究新方向

梁惠康醫生

利國偉腦神經學副教授(中風中心主任)

梁惠康醫生致力透過顱內多普勒超聲波、磁力共振、電腦掃描和3D血管造影等不同的非入侵性影像分析，解開中風演變的謎團。他與國際研究者緊密合作，從顱內血管狹窄的遺傳學背景，深入了解亞洲人中風演變的過程。梁醫生旨在透過病人的基因排序，為病者制定風險預測和合適的個人化治療。另外，他亦進行腦血管阻塞的支架植入和使用ischemic stroke system(ISS)增加腦部血管流量兩項介入性治療研究。

梁醫生對中風診斷和治療的改良一直充滿熱忱；他與香港理工大學醫療科技及資訊學系合作，發展出遠程中風溶栓治療服務系統，利用流動影像傳訊，協助腦神經科醫生在非辦公時間為中風病人評估和診斷。這系統有助紓緩腦神經科醫生短缺和改善中風病人的治療成效；而革新的技術獲頒發2013年亞太區HIMSS-Elsevier數碼醫療傑出資訊及傳訊技術獎。

談到未來的挑戰，梁醫生期盼有更多推廣去鼓勵病人參與臨床試驗。「病人的積極參與，促進研究者對疾病了解和治療發展；沒有他們的支持，我們對中風只是皮毛認識而已。」

探索新領域的年青研究者

劉玉麟醫生

內科及藥物治療學系助理教授；香港中文大學中西醫結合醫務中心副醫務主管

投身在未知領域的研究是充滿挑戰性！劉玉麟醫生雖曾是黃家星教授的學生，他卻選定以多發性硬化症(MS)為自己的研究方向。

在2012年，劉醫生建立了香港多發性硬化病人的大型資料庫。「對於多年來被忽略的多發性硬化病人，這是新的一頁。」劉醫生指出，這些資料不但使他加深了解MS和其相關症狀，更為本地MS研究提供了穩固的基礎。他的努力獲得香港內科醫學院的肯定，並於2012年贏取年輕研究員資助的撥款。此外，劉醫生得到醫療衛生研究基金(HMRF)的贊助，現與瑪麗醫院免疫學實驗室和其他十間本港醫院合作，進行評估MS病人使用干擾素後產生中和抗體情況的多中心研究。除此之外，他與影像及介入放射學系的Dr. Jill Abrigo緊密合作，開發專為MS設計的MRI標準臨床方案，為病患者提供更全面的疾病監察和研發新型生物標記。

除了常規治療外，劉醫生與中西醫結合研究所的張海藝中醫師合作，以中醫學方式提供綜合治療予MS病者。在一項先導研究中，他的團隊發現早期復發性MS同時出現疲累和氣虛的關聯性很高。下一步，他將會籌劃以針灸治療MS的介入性臨床試驗。

通告

與Pfizer結成伙伴關係 (INSPIRE 研究中心)

在2015年4月，香港中文大學／ 威爾斯親王醫院被Pfizer選定並簽署為INSPIRE (Investigator Networks, Site Partnerships and Infrastructure for Research Excellence)研究中心，這伙伴關係肯定了我們在研究方面的能力與表現。

Pfizer

INSPIRE Sites

Certificate of Approval

This is to certify that

The Chinese University of Hong Kong, Prince of Wales Hospital

Has been selected as

INSPIRE site

(Investigator Networks, Site Partnerships and Infrastructure for Research Excellence)

As of

01st April 2015

Molly Chen
Investigator Site Development Lead

*The certificate is valid for 1 year from the date of approval.

臨床試驗保險申請的新安排

在2015年7月開始，中文大學的臨床研究保險會改為由Newline Asia Services Pte. Ltd. 提供。申請臨床試驗保險可經由CRMO安排。保險覆蓋範圍詳情可參閱中文大學財務處網頁。

每日提要

探討問題 (1) ：是否有處理臨床研究受試者醫療廢物的指引？

關於臨床應用和研究所產生的醫療廢物處理，可參考從CAP 354O－廢物處理(醫療廢物)(一般)規章的基礎上建立的醫療廢物管理計劃(CWMP)。詳情請參閱醫院管理局運作通告No.5/2012號附件，你也可以從CRMC網頁下載 (標準操作規程/醫院管理局 新界東醫院聯網－有關臨床研究之標準操作規程)。

探討問題 (2) ：在威爾斯醫院進行藥物臨床研究，在申請醫院准許時，必須連同藥劑部(臨床研究)(CRP)管理研究藥物同意書一併遞交。什麼是CRP管理研究同意書和怎樣申請呢？

為了確保臨床研究藥物得到安全和質量管理，藥劑部(臨床研究)(CRP)於2015年4月成立。在威爾斯醫院進行藥物臨床研究前，首席研究者(PI)應在籌劃時聯絡CRP，商討該研究藥物的流程管理；而雙方達成協定後便會簽署管理研究藥物同意書。當申請醫院准許時，需附上已簽署的管理研究藥物同意書之副本。此安排只適用於在威爾斯醫院內進行的藥物臨床研究。

探討問題 (3) ：為何研究隨訪必須輸入醫管局(HA)的臨床醫療管理系統(CMS)？

研究者應將研究受試者的資料輸入HA的CMS系統內，使其他的臨床團隊(在同一所或不同的醫院)都能知道病人參與試驗的狀況。另外，也可以避免病人同時參與兩項研究。重要的資料包括研究簡稱、臨床試驗方案編號、CREC編號及首席研究者姓名和聯絡電話應顯示於CMS Alert上，更多細節可撰寫在CMS Reminder內；病人的進展可記錄在會診備忘錄；而病人用藥記錄亦需更新。

重點活動推介

ICH-GCP工作坊

為期一天的GCP工作坊將在本年11月7日再次舉行。培訓是由擁有豐富及全面ICH-GCP經驗的講員教授，訓練獲TransCelerate BioPharma認証，也獲全球不同藥廠研究申辦者的認可。歡迎中文大學和新界東醫院聯網內從事臨床研究少於兩年或對ICH-GCP有興趣認識更多的同事參加。你可從CRMC網頁得悉更多工作坊的詳情和報名。
http://www.crmc.med.cuhk.edu.hk/Whatsnew/EventsandTrainings.aspx

研究者擬定的臨床研究計劃(IST)工作坊

CRMO將會舉辦一系列以IST為目標的午間工作坊。這些工作坊的題目包括：研究經費的申請、臨床試驗方案的建立、預算籌劃和臨床研究的監督。工作坊的對象是對臨床研究有學術興趣的中文大學和新界東醫院聯網內的同事。第一個工作坊將於12月9日舉行，主題包括撰寫研究資助、申請CREC臨床研究倫理認可及其他相關規章的程序和了解臨床試驗保險政策。詳情將於日後透過電郵公佈。

聯絡方法

香港中文大學－新界東醫院聯網臨床研究統籌處

地址: 香港新界沙田銀城街30-32號威爾斯親王醫院呂志和臨床醫學大樓八樓
網址: http://www.crmc.med.cuhk.edu.hk　電郵: crmo@cuhk.edu.hk　電話: (852) 2632 4276

Uniting Asia-Pacific Clinical Research Sites in Melbourne

Society for Clinical Research Sites (SCRS)

SCRS was founded in 2012 as an organization representing clinical research sites globally. SCRS currently represents over 2,400 research sites 40 countries. They unify the voice of the global clinical research site community for greater site sustainability, and hence they emphasize a lot on site engagement, partnership and training.

The Society for Clinical Research Sites is the first advocacy organization for the clinical research site community

The inaugural Asia-Pac Site Solutions Summit (http://apsitesolutionssummit.com) was held in Melbourne, Australia, on 30th Jul- 31st Jul 2015. Organized by the Society for Clinical Research Sites, the Summit covered several contemporary topics related to clinical research, including: the latest technologies being used in clinical research, global initiatives aiming to reduce administrative workload, and global clinical research trend. Representatives from CRMO have also attended this meeting in order to exchange best practice with other institutions. We would like to share some updates with you.

Latest Technologies in Clinical Research

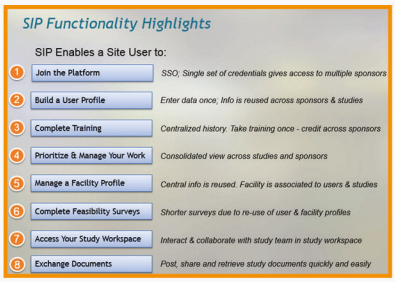
Dr. Hugo Stephenson, Executive Chairman of DrugDev, showcased a number of ongoing technological innovations being tested by different pharmaceutical companies. With the development of eConsent and eSource, patients can now sign on an interactive consent form on a tablet, and the source data captured by nurses can be entered automatically into the case report forms. These platforms can save the research staffs valuable time in explaining the study to the patients and transcribing the source data from one place another. Next, Dr. Stephenson explained the advantages of mHealth and activity tracking devices in clinical research. Instead of using questionnaires and patient diaries, the activity level (e.g. steps and location) of patients can be tracked by the mobile devices with data collected in real time. These data will be particularly useful in pain, behavioral, and rehabilitation research. Not only the data will be more objective, but also can reduce the number of clinic visits.

TransCelerate is Taking Steps Further

TransCelerate BioPharma Inc. is a non-profit organization aiming to facilitate the collaboration between different stakeholders in the clinical research industry. Building on their previous success in harmonizing study site qualification and training, they have recently launched a Shared Investigator Platform (SIP). The SIP is a shared database with crucial investigator site information which can be accessed by multiple sponsors. This database allows the site staff to interact with multiple sponsors with a single point of contact and eliminate the site's burden in performing multiple feasibility assessment with different sponsors. Additionally, TransCelerate is also developing a shared electronic platform with various pharmaceutical companies to reduce the redundancy in electronic systems training and the number of passwords. Currently, the site staffs would need to login to one website for study training, another one for IVRS, a third one to complete the eCRF and yet another one for overseas safety reports. But in the near future, all of the study-related tasks could be performed with only one login.

TransCelerate BIOPHARMA INC.

ACCELERATING THE DEVELOPMENT OF NEW MEDICINES



Global Clinical Research Trend

With clinical research cost on the rise, experts attending the summit expected that more small scale specialty research will be done, fewer study sites will be selected, and more complicated protocols will be used. Investigator sites would need to be more competitive, and establish a reputable track record for them to be selected. Investigator sites shall not be shy to showcase their capabilities and gain more international exposures. Sponsors will be contracting more of their duties to contract research organizations (CROs) and the CROs will take a more prominent role in site selection, quality assurance and contract management. A closer partnership between the investigator sites and CROs would need to be formed to ensure a sustainable future for the sites and CROs.

CRMO is the member of SCRS!

Clinical Research Management Office (CRMO) of CUHK is now a member of SCRS. Please go to the SCRS website http://myscrs.org/ to learn more about SCRS.

Contact us

Joint CUHK-NTEC Clinical Research Management Office (CRMO)

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