Joint CUHK-NTEC CRMO Newsletter

Issue 2: February 2015

Director's Message

2014 is the foundation year of Clinical Research Management Office (CRMO). We are delighted on accomplishing lots of milestones including setting up the CRMO website and database for each research unit, cascading the centralized SOP (Standard Operating Procedures) of clinical research to the whole NTE Cluster, conducting series of trainings, workshops and GCP online tests, as well as attaining the re-accreditation of our current 9 China-FDA (CFDA)-clinical research units in Prince of Wales Hospital (Gastroenterology, Oncology, Endocrinology, Cardiology, Paediatric Haematology, Paediatric Respiratory, Paediatric Immunology, Paediatic Infectious Disease, and BABE - Bioavailability & Bioequivalence). We would like to express sincere gratitude to the support and cooperation of all research units.

CRMO aims at enhancing the clinical research of our cluster hospitals through partnership with investigators and research colleagues as well as other stakeholders such as Department of Health, study sponsors, CROs (contract research organizations) and academic institutions. In the new year, we are evolving from the role focusing on governance and compliance of clinical research to a dual balancing directions on both "quality and compliance" as well as "efficiency and competitiveness" of our clinical research. With centralization & integration of competency, knowhow and resources of clinical research, our research activities can be flourished and further expanded.

Quality & Compliance

SOP
- Create, update, implement

Training
- GCP
- SOP

Inspection
- Internal site inspection
- Communicate with auditors and inspection (e.g. CFDA)

Monitoring
- Study database
- Report analysis
- SAE & AIRS

Efficiency & Competitiveness

Coordination & Liaison
- Internally with PI/ research nurses/ CRP/CREC/ ORKTS/ HA Legal
- Externally with DOH/ CFDA/ Study Sponsors/ CROs/ other stakeholders

Consultation
- PI: For IST
- Study Sponsor/ CRO

Centralized service
- File Archiving
- Training resources

Competency
- Sharing of expertise
- Training: Study planning, technical, resuscitation

CRMO belongs to every single of us involving in clinical research in NTE Cluster. We appreciate all valuable advice and suggestions.

Wish all of us a prosperous, fruitful and healthy Year of Sheep!

Regards,

Iris Chan
Managing Director
Clinical Research Management Office (CRMO)

Events & Activities

Delegation Visit of Sun Yat-sen University Cancer Center

CRMO received delegates of Sun Yat-sen University Cancer Center in Nov 2014. During the visit, we exchange ideas and experience on the development and application of CRMO website and database system.

ICH-GCP on-line Examination

Another round of online GCP certification examination was arranged between 22nd Dec 2014 and 9th Jan 2015. Sixty-seven (67) of our colleagues have attempted the examination and 57 have passed with score ≥80%. Colleagues especially who are new to clinical research are welcomed to attend the upcoming ICH-GCP workshop in March.

Highlight of Research Unit

Cheshire Home Shatin (SCH) **aims at improving the patient care and tailoring new solutions to patient's unmet needs by clinical research. We have interviewed different colleagues in SCH to share their experience and aspiration.**

CRMO: How do you motivate your colleagues to conduct clinical study under limited resource in a non-academic hospital?

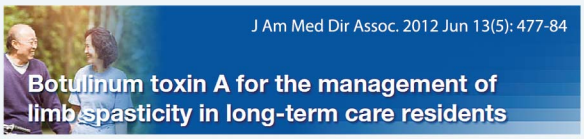
Dr. Herman Lau (HCE): Our vision is to strive SCH as the center-of-excellence in rehabilitation and infirmary care. With our strong culture of managing patients in multidisciplinary approach, we encourage research ideas from different disciplines and the research proposals are discussed in hospital management committee (HMC). Through clinical research, we aim at generating evidence-based data and improving quality of life of patients. Recently, we presented a study named "A retrospective study to review the effectiveness of a low-load prolonged stretch program for preventing elbow flexion contractures in high-risk long-term care residents" as an oral presentation in HA Convention 2014. We will look for more cross-disciplinary and multi-center partnership on local and international research of infirmary care.

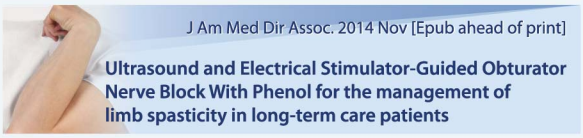
CRMO: Why do you insist to conduct clinical study when there are only 2 doctors in SCH?

Dr. Lam: It is always my calling to serve the underprivileged group of the medical system, and I am always passionate on clinical research. I am grateful for the strong support from the Hong Kong Cheshire Home Foundation, and the management of SCH including the former HCE share similar vision and always provide affirmative support on clinical research.

CRMO: Can you share your happiness about your recent studies on Botulinum toxin and phenol nerve block which has gained significant international recognition as well as media awareness?

Dr. Lam: I am happy that these studies significantly reduce my colleagues' burdens with improved scores on patient-centered outcome measures. Through our regular injection sessions, colleagues from various rehabilitation centers as well as medical and neurosurgical departments can come to share the knowledge of injection skills and exchange their experiences.





CRMO: SCH is conducting a 2-year survey on safety attitudes among the staff. Can you share about this survey?

Ms. Wong (Physiotherapist): We hope to understand the safety attitude among our colleagues using Safety attitudes questionnaire (SAQ). With the data, we are now proposing strategies such as establishing effective and bi-directional communications channels, holding game booth for promoting safety culture, and publishing newsletters. We expect a sustainable improvement of our safety culture which can be illustrated in the 2nd and 3rd wave of survey in coming years.

Highlight of Research Unit

CRMO: We notice that the seats of non-ambulant patients are different among each other. How do you decide on the proper position of the seats for each patient?

Mr. Yui (Occupational therapist): Non-ambulant patients easily develop pressure sore. With the use of pressure mapping, we can accurately adjust the tilting angles of the seats in order to minimize the pressure exerted on each patient. They can have more opportunity to sit out or go around on wheel chair now.

CRMO: We know that there is a special emollient derived from a previous study of SCH for the elderly of SCH. Can you tell us more about this?

Ms. Tsang (Nurse of Infirmary Unit): As the commercial skin ointment cannot improved our elderlies' cracked skin, our nurse developed an emollient and conducted a clinical trial on this. We are glad that the results are positive.

CRMO: What are the key challenges of clinical study?

Ms. Tsang: Clinical study usually involves change in habits, and people may be resistant to change. We may introduce the change in stepwise manner using a pilot run-in program so they can gain positive experience and hence are motivated to join the study.

We are grateful to have a team of passionate colleagues in SCH who are dedicated to individualize the management of patients with various disability, while they are also eager to share their clinical experience through clinical research with other healthcare professionals.

Tips of the Day

Case Scenario 1: If the study sponsor financially supports the PI to archive study documents in the offsite document storage facility offered by CRMO, can the study sponsor retrieve or transfer those documents to another place in the future?

The retrieval and transfer of study document can only be made by the PI, so the study sponsor need to obtain prior written consent from PI before such relocation of document can be made. ✓✓

Case Scenario 2: A subject was invited to join a clinical study. He was asked to fill in a patient questionnaire and his blood was taken BEFORE signing informed consent form (ICF). Are these procedures appropriate?

ICF should be signed and dated by the subject and the PI/ delegate BEFORE any study procedure is carried out. If patient questionnaire answering and blood test taking are parts of the study procedures listed in the study protocol, the above-mentioned sequence is incorrect. For details, please refer to CRMO-SOP-011. ✓✓

Case Scenario 3: What should a research staff do if the storage conditions of IMPs (investigational medicinal products) are not specified on the IMP packaging?

Before the study starts, research staff should confirm with study sponsor and document in writing about the storage conditions (including temperature & relative humidity) of IMP. If there is any derivation from the storage conditions specified, the staff should inform study sponsor immediately to confirm if the IMP can still be used. You may refer the details about the management of IMP in CRMO-SOP-007. ✓✓

Announcements

Update of CRMO website about two new add-on functions

1. Uploading study documents (Optional)

Website coordinator of each research unit can now upload study files (e.g., study protocol, patient informed consent, study flowchart, etc – in PDF file up to the file size of 5MB) of each registered clinical study for access of selected research personnel so they may make reference to the study documents anywhere with internet access. This function of uploading study documents is optional for each study.

2. Report Generation

All registered users can generate reports of their own research units to overview the current status of ongoing studies, not-yet-started studies, new studies, and completed studies. Different criteria, e.g., type of sponsorship, type of study can be selected to tailor their reports.

Inspection

Inspection on research sites have been started since 4th quarter of 2014, and will be conducted regularly to strength the competency and to reinforce the clinical trial compliance.

Upcoming Events

ICH-GCP Workshop

An one day GCP workshop is scheduled on 7th Mar 2015 for our colleagues who have less than 2 years of experience in clinical research or who would like to learn more about ICH-GCP. This GCP training will be conducted by investigators and other clinical research professionals who have extensive experience in the field. The training will be recognized globally by various study sponsors. Details are announced on CRMO website.

Resuscitation BLS training

With the great help from Prof. David Chung and the staffs of the Kai Chong Tong Clinical Skills Learning Centre, several half-day resuscitation workshops are going to be hosted this year. Our clinical research staffs can have their resuscitation skills refreshed and updated with content tailor-made for local hospital setting. Due to limited capacity, the first resuscitation workshop will only be prioritized to research units applying for CFDA accreditation in 2015. Details are announced on CRMO website.

SOP on-line training

From Mar 2015, CRMO registered users will be able to go through CRMO SOP training through audio guidance on CRMO website. Training certificate will be updated in their CRMO training record after online training. Details will be announced by CRMO.

Resuscitation

Sharing

For any enquiry or experience concerning the GCP practical issue(s), you are welcomed to email us and share with our readers.

Contact us

Joint CUHK-NTEC
Clinical Research Management Office
(CRMO)

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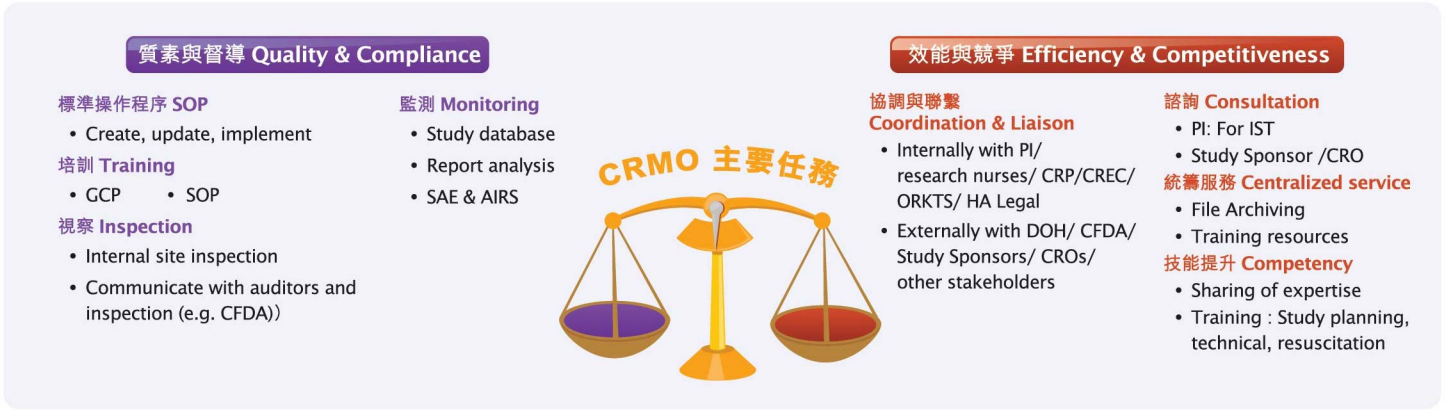
香港中文大學－新界東醫院聯網臨床研究統籌處通訊

第二期：2015年2月

處長的話

2014是臨床研究統籌處（CRMO）生氣勃勃和精彩的一年；在過去一年，我們建立了CRMO網址和電子資料庫，為各臨床研究單位提供了綜合的網上平台；同時，我們為新界東聯網醫院的臨床研究製訂了一套標準操作程序（SOP），並且舉辦了一系列的培訓、工作坊、藥物臨床試驗質量管理規範（ICH-GCP）線上考試等，幫助同事掌握臨床研究相關的規例和管理。另外，威爾斯親王醫院的9個國家食品藥品監督管理總局（CFDA）認証的藥物臨床試驗專業（包括消化、腫瘤、內分泌、心血管、小兒血液、小兒呼吸、小兒免疫、小兒傳染及生物等效性），再次獲得覆查評估認証。在此，我們衷心感激各研究單位的支持和合作。

我們透過與聯網醫院的研究者（Investigators）和研究團隊及相關的機構如衛生署、研究申辦者（Study Sponsors）、合同研究組織（CROs）和學術機構等聯繫，建立了伙伴關係，加強新界東聯網醫院的臨床研究活動。在新的一年，我們將會由過往較專注臨床研究的管理和督導，逐漸轉向「質素與督導」及「效能與競爭」兩大範疇的平衡。隨著把臨床研究相關的資源及經驗整合和共享，新界東聯網醫院的研究工作將會進一步提昇和發展。



我們期望能與各新界東聯網醫院的臨床研究團隊並肩同行；如有任何建議或意見，歡迎向我們提出。

最後，祝大家羊年百尺竿頭，更進一步。

臨床研究統籌處

陳虹 執行總監

活動剪影

中山大學腫瘤防治中心訪問團到訪

中山大學腫瘤防治中心的訪問代表團於去年11月到訪本處；雙方就開發和應用網頁平台及電子資料庫系統等問題上，彼此分享經驗和交換寶貴意見。

國際協調會議 — 藥物臨床試驗質量管理規範 (ICH-GCP) 線上考試

第二輪線上ICH-GCP考試已於2014年12月22日至2015年1月9日期間舉行。67位應考同事中有57人的分數達80分或以上，成功通過考試。同事如想增加對ICH-GCP的認識，可參加3月份舉行的ICH-GCP工作坊。

卓越研究團隊掠影

沙田慈氏護養院 旨在提升病人的護理服務質素，因此院內致力推行適切病人需要的臨床研究，尋找更好的方法幫助病人。今期我們訪問了幾位來自院內不同部門的同事，分享他們的經驗和抱負。

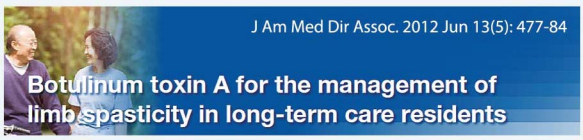
CRMO：作為一間非教學醫院，在有限的資源之下，你（劉院長）如何推動同事們進行臨床研究？

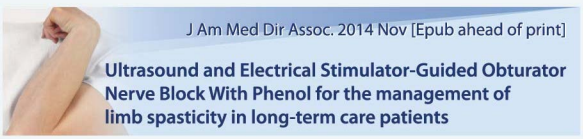
劉院長：帶領本院成為卓越的復康及護養中心是我們各同事的共同願景。不論是日常的復康護養或是進行臨床研究，我們都有堅實的跨部門合作文化。任何同事提出臨床研究的新概念，我們都非常歡迎，並且會將這些概念在醫院管理委員會商討當中的可行性。透過循證臨床研究，我們更有信心把所得的數據運用，從而適切地改善院友的生活質素。在2014醫管局研討大會上，本院同事有機會口述報告一篇名為「探討用矯形器固定患處對有肘關節攣縮的長期護養病人的療效」的研究成果，大家感到非常鼓舞。展望將來，我們期望在護養研究方面能與本地及國際團隊建立更多跨部門、多中心合作的夥伴關係。

CRMO：目前只有你（林醫生）和另一位醫生為300位病人提供醫療診症，有什麼推使你在百忙中仍堅持進行臨床研究的工作？

林醫生：我的呼召是服務在現今醫療體制下被忽略的一群，我希望以自己對臨床研究的熱誠，能為這群體提供更適切的醫療服務，幫助他們；我很高興現任院長，前任院長和醫院管理層與我有相同的抱負，和樂意提供實質的幫助，我也非常感激香港慈氏安養基金會的全力支持。

CRMO：你最近兩篇關於使用肉毒桿菌素及閉孔神經作酚注射的臨床研究報告，均得到國際的肯定和本地傳媒的關注，可否概述研究的成果和當中的喜悅？





林醫生：我很高興這兩項研究能有效減輕照顧者的負擔及改善病人的生活質素。透過定期的注射研習環節，我們能和不同的復康中心、內科及腦外科的同事們，分享注射技術和交流相關經驗，這些都是非常難得的機會。

CRMO：為何你們有進行為期兩年的「安全意識」問卷調查的構思？

黃姑娘（物理治療部）：我們邀請院內同事填寫「安全意識問卷」，以了解同事對安全的看法。透過數據分析，我們制訂一系列的策略，例如建立有效和相互溝通的渠道、舉行攤位遊戲和出版通訊等，在院內共建安全文化。我們期望在第二和第三輪的問卷調查中，看到院內的安全文化能持續提升。

卓越研究團隊掠影

CRMO：院內行動不便病人的輪椅，座位和角度都不盡相同，你如何決定出最合適病人的坐椅位置？

芮先生（職業治療部）：行動不便的病人容易因受壓而致壓力瘡，我們使用壓力量度儀，就能為病友的座位調較出合適角度和坐椅時間，減輕受壓部位的壓力，增加他們坐起或外出的機會。

CRMO：你們為院友研製出一種潤膚軟膏，是什麼原因誘發大家作出嘗試？

曾姑娘（護養部）：因市面上的潤膚軟膏未能有效改善年老病人皮膚因乾燥而致爆裂的情況。有見及此，我們的同事進行臨床試驗，終於調製了一種成效顯著的潤膚軟膏；能夠幫助病友，大家都感到高興。

CRMO：你覺得推動臨床研究最大的挑戰是什麼？

曾姑娘：進行臨床研究意味著改變，一般而言，人通常抗拒改變。所以我們會採用先導計劃的形式，按步就班推行，透過獲得正面的經驗，推動同事一起參與。

我們很感謝沙田慈氏護養院一群充滿熱誠的同事獻身於服務殘障病人，並且樂意將臨床研究的經驗與其他醫護同事分享。

每日提要

個案事例（1）：如臨床研究申辦者（Study Sponsor）贊助首席研究者（PI），將臨床研究文件放到CRMO提供的文件儲存公司存放，該研究申辦者日後能否自行提取文件或轉換儲存地方？

提取臨床研究的文件或轉換儲存地方只可由首席研究者決定。研究申辦者必須先得到首席研究者的書面同意，才可以提取或轉換儲存地方。 ✓✓

個案事例（2）：病人被邀請參加臨床研究。他經過抽血檢查和完成臨床試驗問卷後，才簽署知情同意書。這是一個合適的程序嗎？

在進行任何與研究有關的步驟前，病人和首席研究者（或其代表）必須在知情同意書簽署及註明日期。如果填寫臨床試驗問卷或抽血等步驟列於研究試驗方案內，以上所提及的程序是錯誤的。詳情請參閱CRMO-SOP-011。 ✓✓

個案事例（3）：臨床研究職員發覺由研究申辦者提供的臨床研究藥物上沒有標明儲存的條件，他們應該怎樣處理？

在臨床研究開始前，臨床研究職員必須向研究申辦者確定研究藥物儲存所需條件（包括溫度和相對濕度），並以書面形式記錄在案。假若發覺藥物儲存狀況跟所標示的條件有差異，就應該立即與研究申辦者聯絡，查詢該藥物能否繼續使用。關於管理研究藥物的詳情，請參閱CRMO-SOP-007。 ✓✓

通告

CRMO網頁兩項新增附加功能：

1. 上載研究文件檔案（自願性選用）

為方便研究人員隨時參閱有關研究檔案資料，研究單位的網頁協調員（Website coordinator）可為已登記的研究上載相關文件（例如：研究方案、病人知情同意書、作業流程圖等。每一文件大小以5MB PDF形式為上限），及可選擇能取閱的研究人員。這項上載研究文件檔案功能是自願性選用。

2. 簡報製作

各研究單位可選擇不同之項目（例如：研究申辦者、研究類型等），分析臨床研究（包括所有進行中、未展開、新展開或已完成等的研究項目）之狀況及編製簡報。

視察

為提升各研究單位的競爭力，幫助相關工作人員能恒常依從各臨床研究規範的要求，我們於去年第四季起展開了臨床研究單位的視察工作，並會於將來定期到各研究單位進行視察。

重點活動推介

ICH-GCP工作坊

為期一天的ICH-GCP工作坊將會在2015年3月7日舉行；是次工作坊對象是從事臨床研究少於兩年或有興趣認識更多ICH-GCP的同事。工作坊的導師包括來自對ICH-GCP有豐富經驗的研究者和相關專業人士；這項訓練亦獲全球不同藥廠研究申辦者所認可。詳情已於CRMO網頁公佈。

急救復甦（Resuscitation）工作坊

CRMO得到張志偉顧問醫生和繼昌堂臨牀技術學習中心同事的幫助，今年內將會舉辦數次為期半天的「急救復甦工作坊」。工作坊的內容是因應醫院環境而設計，以提升和更新各臨床研究同事的急救復甦技術。由於場地空間有限，首輪工作坊的名額會優先給予現正申請CFDA認可的研究單位。詳情已於CRMO網頁公佈。

標準操作程序（SOP）線上訓練

已登記用戶於三月起，可隨時在線上複習輔有語音導讀的SOP訓練；完成訓練後，證書將自動更新於CRMO網址內之用戶的訓練記錄。詳情請留意CRMO日後公佈。

公開園地

歡迎同事就GCP的實踐經驗或疑問以電郵方式聯絡我們，供大家分享交流。

聯絡方法

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