Joint CUHK-NTEC CRMO Newsletter

Issue 6: Jul 2016

Director's Message

Dear colleagues,

The advance of medicine requires high quality clinical research to test the values of new diagnostic or therapeutic methods. Prince of Wales Hospital (PWH) is the teaching hospital of The Chinese University of Hong Kong. Since the clinical service of PWH was started in 1984, it has been a very active site in various types of clinical research, from observational studies to intervention studies. Since the formation of Cluster service in New Territories East (NTEC) in 1990s, the CUHK research activities also extend to other HA hospitals in NTEC. We are glad to note that academic staff of CUHK have produced very high impact clinical research in the past three decades. Many HA staff are also actively engaged in the clinical research, either as co-investigators in studies led by CU colleagues, or taking up the active role as principal investigators in many clinical research studies.

The Joint CUHK-NTEC Clinical Research Ethics Committee was established in early 2000s. Hospital Authority requested the two university teaching hospitals to set up joint CREC or IRB with the cluster hospitals because patients recruited into the studies are mostly HA patients. The Joint CUHK-NTEC CREC has worked smoothly in the past years in reviewing and vetting the research applications. The top priority of CREC is to protect patients' safety during the clinical research.

There are now over 600 research studies approved every year and over 100 being intervention studies. Some intervention studies are company-sponsored clinical trials, the pharmaceutical companies perform very stringent monitoring of the sponsored trials. We are now encountering more and more investigator-initiated studies in the cluster. In the past two decades we had few incidents related to clinical research. The NTEC management had drawn up some guidelines to enhance the research safety. The China FDA accreditation and HA hospital accreditation had been the driving force to set up a management body on clinical research in the Faculty and the Cluster. With support from Cluster Chief Executive and Dean of Faculty of Medicine, the Joint Clinical Research Management Committee (CRMC) was established in 2013. The objective of CRMC is to develop policies to govern the clinical research conducted in NTEC, and also monitor and ensure compliance with policies pertaining to clinical research.

After the establishment of CRMC, we set up two important offices under CRMC: Clinical Research Management Office (CRMO) and Clinical Research Pharmacy (CRP). Under the leadership of Professor Juliana Chan, CRMO has prepared a full set of Standard Operation Procedure (SOP) on various aspects of research operation, from governance to record keeping. This is a very important system that all the clinical departments can now take reference of these SOPs to prepare their own set of SOPs within the departments. Training is an essential component for planning and implementation of clinical research. CRMO has organized online training courses and luncheon workshops for staff in the Cluster and the Faculty, over 400 staff attended the workshops in 2015. CRMO and CRP, and also with CREC have jointly arranged audit of clinical research studies, initially at the CFDA accredited sites and then extended to other investigator-initiated trials.

Investigational Medicinal Product (IMP) can be pre-licensed or licensed products which may not be part of the regular clinical management. Using IMP is not without risk as these products may not be included in our existing management mechanism of pharmaceutical product, say from storage to administration. CRP was set up to have central coordination and management of IMPs which were previously managed at different sites under the PIs. With the help from CRP, we are now having a safe mechanism in the IMP management which will reduce the risks related to IMP.

Conducting clinical research requires good governance system. I am proud to say that the quality of clinical research in NTEC and CUHK has shown marked improvement in past few years. We have received rating of Extensive Achievement (Research) in the 2013 hospital accreditation. The prime objective of research management is to protect patients' safety and I believe all colleagues share the same objective. I must express my sincere gratitude to all colleagues of CRMC, CRMO and CRP whom have done tremendous work to improve our research quality and safety. Finally we need your continuous support and cooperation to achieve the highest standard of clinical research.

Dr. Li Chi-kong,
Chairman, Joint CUHK-NTEC CRMC

CRMO Inspection of Clinical Research Units

To ensure that our clinical research activities are complying with ICH-GCP, CUHK-NTEC CRMO SOPs, and relevant regulations, a Clinical Research Inspection Team was set up in June 2015. To date, eight inspection and six pre-CFDA inspection exercises have been performed. Constructive exchanges were seen during the inspections and we would like to thank all the inspected units of their patience and cooperation during the inspections.

During our inspections, all non-compliances would be recorded as findings which required corrective actions. Inspection findings were graded into three levels: critical, major and minor. Critical findings included those non-compliances which will affect the safety of the study subjects or the integrity of the study data. Major findings are those non-compliances which may affect subject safety and data integrity. Minor findings are those non-compliances which would have no effect on safety or data integrity. All critical findings will be reported to the Joint CUHK-NTEC Clinical Research Management Committee and Clinical Research Ethics Committee for further actions, if needed.

We would like to take this occasion to remind our investigators and research teams that extra attention shall be paid in the following areas:

Informed Consent Process:

- All study procedures, including vital signs, weight and height measurements, should only be carried out after all relevant parties have signed on the informed consent forms.
- Justifications shall be provided for the recruitment of patients incapable of provided consent.
- Informed consent forms shall be personally dated by the study patient.
- The most updated and approved version of informed consent form shall be used.

Safety Reporting:

- All serious adverse events (except for those exempted in the protocol) shall be reported to our CREC within 24hrs of notification.
- CREC has updated their SOP in April 2016. All SAEs described in the study protocol as exempted from reporting will not be required to report.
- All adverse events shall be reviewed by a medically qualified investigator with severity and causality determined.
- Sufficient medical care and follow ups shall be provided to all study subjects, especially those with adverse events.

Study task delegation:

- Only persons delegated by the principal investigator can perform study related tasks.
- All study team members should have received appropriate training for the tasks which they have been delegated for.
- Current curriculum vitae and training records of all study team members should be maintained at the study site files.
- The principal investigator is the person who ultimately takes full responsibility of the study. Only duties can be delegated, not responsibilities.

Again, thank you for all the inspected units of their time and effort making the inspections possible. The inspections and exercises gave us the opportunity to better understand the research practices of different units and the hurdles they encountered day to day.

CFDA accreditation

There are 9 CFDA accredited clinical research units in PWH since 2006, and these units go through vigorous re-accreditation inspection every 3 years. With the expansion of clinical trial activities and collaboration with China, 6 additional specialties and Phase 1 Clinical Trial Centre have submitted application as CFDA accredited clinical research units in 2015.

Five inspectors from CFDA and four pharmacists from Drug Office of Department of Health of Hong Kong have conducted an extensive inspection on 3-4 March 2016. The inspection cover the fields including but not limited to the clinical research overall management and governance, research facilities, personnel qualification and training as well as compliance of our clinical research activity on GCP, SOP and study protocol. Upon very constructive and fruitful exchange and discussion with the inspectors, they have provided valuable advice and suggestion on enhancing the clinical trial management and compliance.

After the inspection, CREC, CRMO and CRP have updated several SOPs in order to strengthen the directives on clinical research. Training workshops have been conducted to explain the SOPs, followed by assessment by written tests. For more details about the updated SOPs, please refer to CRMC (http://www.crmc.med.cuhk.edu.hk/CRMCApps/CRMOSOPs.aspx) and CREC (http://www.crec.cuhk.edu.hk/standard-operating-procedure) websites.

Tips of the Day

Q1: When a subject withdraws from a study, how to handle his/ her data?

When a subject withdraws his consent from participating the study, or he/ she is halted by the investigator as the subject fails to fulfill the requirement of the protocol, the data that already obtained should be maintained. The collected data should also be included in the following analyses if appropriate.

Q2: What are the keys in obtaining consent from an unconscious subject?

For unconscious subject, the informed consent of his/ her legally authorized representative shall be obtained and the "Subject's Signature" section should be signed by the legal representative. The process should be documented in the subject's medical record.
When the subject becomes available of giving consent, informed consent shall be obtained again from the subject to determine if he/ she would continue to participate in the study.
You can refer CRMO-SOP-011 and HA Handbook- Clinical Research Management and Compliance at Study Sites for details.

Past and Upcoming Workshops

Clinical Trial Management Workshop for Investigator-Sponsored Trials

The second Clinical Trial Management Workshop for Investigator-Sponsored Trials was held on 5 May 2016. Focusing on protocol and informed consent form (ICF) design, topics covered clinical study design, ICH-GCP requirements on clinical study protocols and ICFs. Common problems in protocol and ICF developments were also discussed. Thanks to all participants for their time and inputs.

Experience Sharing on Multi-Disciplinary Clinical Research

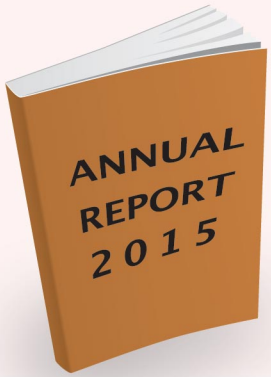
A workshop on multidisciplinary clinical research will be held on 28 July 2016. Prof. Justin Woo and Dr. Edwin Hui will be sharing their experiences in conducting clinical studies in collaboration with other clinical specialties. With their know-hows and insights, our research units will surely be enlightened by the two seasoned investigators.

Advanced Life Support Training

With the great help from Prof. David Chung and the staff of the Kai Chong Tong Clinical Skills Learning Centre, we are glad to announce that an advanced level life support workshop will be organized on 21 October 2016. This workshop is tailor made for clinical research staffs of CUHK who would like to advance their life support training beyond the basics. The workshop will be a whole day workshop and only available to staff members who had previously completed the Basic Life Support training. For more interactive discussion, the class is limited to 4-6 participants per class.

For update, details and registration of our workshops, please stay tuned our announcement at CRMC website (http://www.crmc.med.cuhk.edu.hk/Whatsnew/EventsandTrainings.aspx) and email.

Announcement



CRMC Annual report 2015

The CRMC Annual Report 2015 is now available on CRMC website. The report summarizes the establishment background of CRMC and its mission and vision in enhancing the research quality of CUHK-NTEC clinical research. Under the leadership of CRMC, Clinical Research Pharmacy (CRP) has officially started the service since April 2015. The report also reviewed various training activities and governance measures conducted by CRMO. To download the report, please go to http://www.crmc.med.cuhk.edu.hk/en-us/aboutus/crmcannualreport.aspx .

Contact us

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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

第六期：2016年7月

總監的話

各位親愛的同事：

醫學的進步有賴高質素的臨床研究，測試新的診斷或治療方案的價值。威爾斯親王醫院是中文大學的教學醫院。自1984年投入服務至今，威爾斯親王醫院由觀察性到干預性的臨床研究，在各個不同的範疇上是一個活躍的臨床試驗地點。自1990年代新界東醫院以聯網方式提供服務開始，中文大學的研究活動亦延伸及其他新界東聯網醫院。我們很高興目睹中文大學的學術人員在過去的三十年，進行了很多具影響力的研究。醫管局同事亦以合作研究者角式參與由中大同事牽頭的研究，或更積極地以首席研究者身分投入臨床研究。

中文大學－新界東醫院聯網臨床研究倫理聯席委員會(CREC)於2000年代早期成立。由於臨床研究所招募的對象大部份來自醫管局病人，醫管局要求兩間大學的教學醫院與聯網醫院共同成立CREC或機構倫理委員會(IRB)。在過去多年，CREC一直暢順地審閱和評審各研究申請。保障病人在參與臨床研究時的安全是CREC重中之重的工作。

現時每年審批的研究超過600項，而當中超過100項為干預性的研究。部份干預性臨床研究屬藥廠贊助形式，藥廠會進行非常嚴格的監控。現在我們有愈來愈多由研究者發起的臨床研究。在過去的二十年裏，我們甚少出現涉及臨床研究的事故。然而，NTEC管理層已制定了準則，以提高研究的安全性。國家食品監督管理總局及醫管局的認證推動管理機構的成立，管理醫學院及聯網醫院內的臨床研究。有賴東聯網行政總監及中大醫學院院長的支持，CRMC於2013年成立。CRMC目標在於制定政策，管理NTEC內的臨床研究，並監督及確保遵守有關臨床研究的政策。

成立CRMC之後，我們轄下的兩個重要的部門：包括臨床研究統籌處(CRMO)和藥劑部(臨床研究)(CRP)亦隨之開設。在陳重娥教授的領導下，CRMO已編寫了一整套標準操作規程(SOP)，適合用於由監管到保留記錄等各與研究有關的操作，所有臨床部門都可參考這套SOP以編寫適合各自部門的SOP。培訓是計劃及執行臨床研究中重要組成部份，CRMO為聯網及院內同事籌辦了網上培訓課程及午間工作坊，於2015年已有超過400位同事參加過CRMO的工作坊。此外，CRMO、CRP聯同CREC聯合安排稽查活動，稽查對象包括已獲CFDA認証的試驗地點，並延伸到其他研究者發起的臨床研究。

臨床用藥品(IMP)包括未批準發牌或已批準發牌之藥物，而這些藥物未必於常規臨床使用。由於IMP由儲存到用藥並不納入現有的管理機制中，所以使用IMP需額外謹慎。CRP的成立是把原本於各研究試點由首席研究者管理的藥品將之由CRP作中央管理。CRP令管理IMP的機制更穩妥，減少相關的風險。

開展臨床研究需要良好的管理體系。我可以很自豪地說，NTEC和中大臨床研究的質素在過去幾年已有顯著的改善。於2013年，我們在醫院認証的「研究計劃」中獲得「優異級別」的佳績。管理研究的主要目的是保障病人的安全，我相信所有的同事都朝着這個目標而努力。我衷心感謝CRMC，CRMO和CRP全體同仁在改善我們研究的質素和安全所下的努力。最後，我們繼續需要你們的支持和合作，為達到臨床研究的最高標準而努力。

中文大學—新界東醫院聯網 臨床研究管理委員會主席
李志光醫生

視察研究單位

為確保中文大學-新界東醫院聯網的臨床研究能遵從ICH-GCP，CRMO SOPs及相關法規，臨床研究視察團隊於2015年6月正式成立。迄今我們進行了八次視察及六次CFDA視察前演習。期間，雙方都有建設性的交流。藉此，我們多謝各接受視察的研究單位的合作。

所有不合規及需要糾正的發現項目(finding)都會被記錄在案。視察結果分別為「嚴重(critical)」，「重要(major)」和「次要(minor)」三個層次等級。我們根據該發現項目是否對受試者的安全和研究數據的完整性構成影響，來釐定所屬等級。所有屬於「嚴重(critical)」的發現項目會向CRMC和CREC報告，或需要採取進一步行動。

在此，我們提醒各研究者及研究單位份外留意以下幾方面：

知情同意過程

- 所有與研究有關的程序，包括記錄生命表徵、度高、磅重等，要待有關各方簽署知情同意書後方可進行。
- 如需招募不具有進行知情同意能力的受試者，需提供充份理據。
- 知情同意書的日期該由病人親自填寫。
- 應使用最新批准的知情同意書。

安全通報

- 所有嚴重不良事件SAE(除已在試驗方案豁免之外)應在知悉後24小時內向CREC通報。
- CREC的SOP於2016年4月作出修改。所有已在試驗方案豁免的SAE將不須通報。
- 所有不良事件之嚴重程度和因果關係應由具有醫生資格的研究者作出判斷。
- 應向所有受試者，尤其是那些曾出現不良反應的受試者提供足夠的醫療服務及跟進。

委派研究工作

- 只有獲首席研究者委任的人仕方可進行與研究有關的工作。
- 所有研究團隊成員應就被委派的工作接受適當的培訓。
- 所有研究團隊成員當前的履歷和培訓記錄應放在研究文件夾(ISF)內。
- 首席研究者是整個研究的最終負責人。首席研究者可以委派工作給其他人，但不能把責任交托他人。

在此我們再一次感謝各研究單位付出時間和努力，使視察得以順利完成。現場視察使我們有機會更了解各研究單位的研究工作及日常所遇到的難題。

國家食品藥品監督管理總局 – 藥物臨床試驗機構資格認定申請

自2006年，威爾斯親王醫院已有9個專業獲得國家食品藥品監督管理總局(CFDA)之藥物臨床試驗機構資格認定，而這些專業每三年需經過詳盡的覆核檢查才可繼續獲資格認定。隨着臨床研究活動包括與中國的合作越來越活躍，再有6個專業及一期臨床研究中心於2015年向國家食品藥品監督管理總局遞交藥物臨床試驗機構資格申請。

國家食品藥品監督管理總局於2016年3月3至4日派出5名專家組成檢查小組，聯同4名香港衛生署藥物辦公室藥劑師到威爾斯親王醫院作現場檢查。檢查小組分別對臨床研究組織管理制度、研究設施、人員資歷和培訓、及臨床研究時對臨床試驗質量管理規範 (GCP)、 SOP和臨床試驗方案的遵從性作考核和檢測，亦透過建設性的交流和討論，提出有關加強臨床試驗管理和法規遵從的寶貴意見和建議。

隨後，CREC，CRMO和CRP更新了部分SOP以加強對臨床研究的指引，亦舉行了SOP培訓及培訓後評定。有關SOP更新的詳情，可參考CRMC(http://www.crmc.med.cuhk.edu.hk/CRMCApps/CRMOSOPs.aspx) 及CREC (http://www.crec.cuhk.edu.hk/standard-operating-procedure/) 網頁。

每日提要

探討問題 (1) ：若受試者退出臨床研究，我們應如何處理已獲取的研究數據?

若受試者決定退出臨床研究，或因未能符合試驗方案要求而被終止繼續參與，在退出研究前所獲得該受試者的數據將被保留及在適用的情況下納入往後的分析。

探討問題 (2) ：從昏迷病人獲取知情同意需注意什麼關鍵事項?

昏迷病人的知情同意可向其法定代理人獲得，而“受試者簽署”一欄可由該代理人代為簽署。整個過程必須在病人的醫療記錄內記錄在案。當受試者有能力進行知情同意，整個知情同意需重新進行，並讓受試者決定會否繼續進行該臨床研究。有關詳情，你可參閱CRMO-SOP-011及醫管局參考資料(HA Handbook- Clinical Research Management and Compliance at Study Sites)。

工作坊剪影和預告

研究者擬定的臨床研究計劃(IST)工作坊

第二個IST工作坊已於2016年5月5日舉行。是次工作坊集中討論試驗方案和知情同意書的設計，內容涵蓋如何擬定臨床研究計劃及ICH-GCP對試驗方案和知情同意書的要求。當中也討論在草擬試驗方案和知情同意書常遇到的問題。在此感謝各位的參與和投入。

管理跨部門合作臨床研究經驗分享工作坊

有關跨部門合作臨床研究的工作坊將於2016年7月28日舉行。胡志遠教授和許斌醫生將分享與其他臨床專科部門合作進行臨床研究的經驗。憑藉他們的知識和見解，我們各研究單位定能從這兩位富經驗的研究者身上獲得啟發。

高級心肺復甦法(ACLS)培訓

多謝繼昌堂臨床技術學習中心張志偉教授及其團隊的幫忙，ACLS工作坊將於2016年10月21日舉辦。這個工作坊為有志於心肺復甦法上有進一步認識的中大臨床研究人員度身訂造。是次之全日培訓課程只接受曾完成初級心肺復甦法訓練的同事申請。為使工作坊有更多互動討論，這班僅限4-6人參加。

有關工作坊的最新消息、詳情和報名方法，請密切留意CRMC網頁(http://www.crmc.med.cuhk.edu.hk/Whatsnew/EventsandTrainings.aspx)及電郵的公佈。

通告

CRMC 2015年度報告

2015年度報告已上載於CRMC網頁。報告總結了CRMC的成立背景，及其在提升CUHK-NTEC臨床研究的質素的願景和使命。在CRMC的領導下，藥劑部(臨床研究)已於2015年4月開始正式投入服務。報告亦就CRMO過往舉辦的各類培訓和管理措施進行回顧。你可於以下連結(http://www.crmc.med.cuhk.edu.hk/en-us/aboutus/crmcannualreport.aspx)下載報告。

聯絡方法

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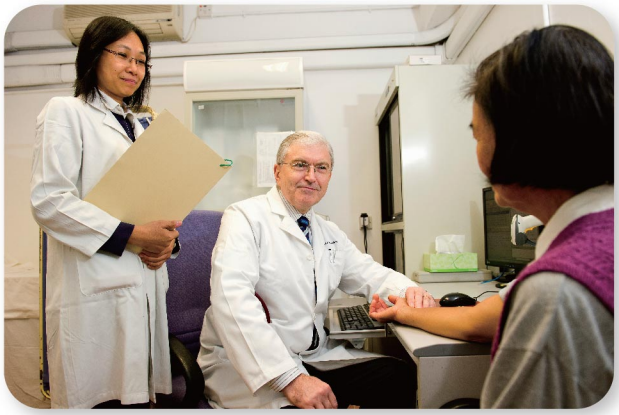
Clinical Pharmacology – Past, Present and Future

Clinical pharmacology is a long established scientific discipline since the early 1900s. It is a multidisciplinary subject involving the discovery of medicinal products, evaluation of their safety and efficacy as well as their clinical application for health protection and disease management. Clinical pharmacologists are clinician scientists who work closely with industry, academia, health care institutions, clinical research organizations, regulatory agencies and other stakeholders to identify clinical needs, personalize drug choices and evaluate novel therapy for registration for widespread usage.



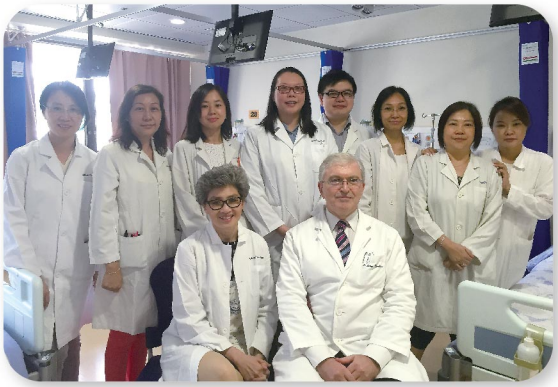
The Clinical Pharmacology Study Unit (CPSU) is the first clinical research unit dedicated to the study of drugs in human beings in Hong Kong. Led by clinician scientists and supported by pharmacists, nurses and technologists, the CPSU has conducted the first pharmacokinetic and pharmacodynamic studies of medicinal products in Hong Kong Chinese. Some of these data were used by the industry to seek approval by the China Food and Drug Administration (CFDA) for registration in China in the early 1990s. To date, the multidisciplinary team conducts the majority of bioavailability and bioequivalent (BABE) studies of generic drugs produced by local and overseas pharmaceutical companies in Hong Kong. These safety and efficacy data are essential for admission into the Hospital Authority Drug Formulary and are often used for registration purposes for entry into the large market of Mainland China. In 2006, along with other disciplines, the BABE Clinical Research Unit was the first and only accredited by the CFDA.

Working closely with the School of Pharmacy, the clinical pharmacologists also applied their experience in conducting clinical trials to design quality improvement programs to reduce non-adherence, guided by protocols and delivered by a team approach with marked reductions in death and hospitalization rates. These encouraging results have contributed towards the development of many integrated chronic care programs in the Hospital Authority (HA). This large body of scientific work has also put Hong Kong on the map regarding the study of inter-ethnic differences in disease patterns and drug responses as well as implementation of quality improvement programs to bring out the best of technology and clinical expertise.

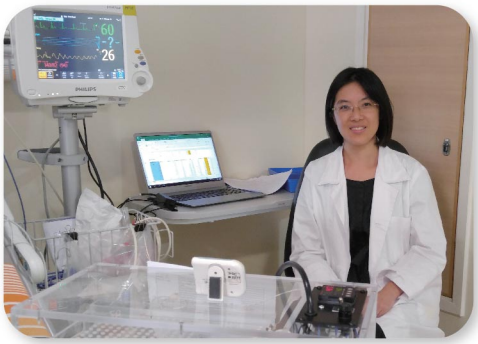
Motivated by the growing burden of cardiometabolic diseases and differences in treatment responses in Chinese compared to Caucasians, clinical pharmacologists of the Chinese University of Hong Kong (CUHK) leverage on their expert knowledge in hypertension, dyslipidemia, toxicology, endocrinology and genetics to conduct some of the pioneer studies in the epidemiology and genetics of metabolic syndrome and diabetes, phase 1-4 clinical trials, drug utilization surveys as well as in pharmacogenetics, pharmacodynamics, pharmacokinetics and adverse drug reactions of common drugs, notably renin angiotensin system blockers and statins in the Chinese population.

The Drug and Poisons Information Bureau (DPIB) was the first service unit in Hong Kong which has provided an infrastructure for the documentation and scientific evaluation of adverse drug reactions of both Western and Chinese Medicines. Since 1989, it has been providing a 24-hour telephone service to the community on enquiries related to drugs and poisons.

In 2005, the Prince of Wales Hospital Poison Treatment Centre (PWHPTC) was jointly established by the Department of Health, HA and the DPIB to provide services and training in clinical toxicology under the directorship of Professor Thomas Chan. Coordinated by Dr. Raymond Wong and Dr. Jones Chan, the clinical pharmacologists have been training internists, providing in-patient and out-patient care as well as consulting the Government on regulatory and public health issues related to drug usage, food safety and environmental toxins.



In line with the Chinese Government policy to promote innovative medicine and leveraging on more than 3 decades of clinical research including drug development and clinical trials in Hong Kong, the Hong Kong Government established the CUHK Phase 1 Clinical Trial Centre (P1CTC) at the Prince of Wales Hospital (PWH) in 2013. Given the state of the art facilities of the Centre, Professor Brian Tomlinson and his CPSU team, who have extensive experience in conducting clinical trials with good clinical practice, has contributed significantly to strengthening the capacity and promoting the reputation of the Centre for conducting early phase clinical trials. The core members of CPSU include Ms. Evelyn Chau (Nursing Officer), Dr. Benny Fok (Scientific Officer), Dr. Tanya Chu (Research Associate) and Dr. Teresa Hu (Research Assistant Professor) and a group of part-time nurses. They conduct, analyze and publish pharmacogenetics studies, BABE and early-phase clinical trials in collaboration with other disciplines.



In 2016, the Clinical Pharmacology team was joined by Dr. Elaine Chow with interests in pathophysiology and drug mechanisms in diabetes and obesity. She successfully translated her extensive experience in conducting insulin clamp studies in UK and introduced this new technique at the Phase 1 Clinical Trial Centre for the first time in Hong Kong. This investigation tool will provide new insights into the relative contribution of insulin insufficiency and insulin resistance in young people with diabetes and prediabetes as well as drug responses in Chinese populations. As Hong Kong enters a new era of knowledge industry, the promotion of Clinical Pharmacology as a scientific discipline will provide new career opportunities for our young doctors, scientists and professional workers to contribute towards the protection of human health through innovative medicine and quality pharmaceutical care. To this end, we look forward to developing partnerships with other disciplines to design, conduct and coordinate various drug development programs including the use of novel biomarkers and devices for predictive, preventive and personalized medicine.

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http://www.mect.cuhk.edu.hk/specialties/clinicalpharmacology.html

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