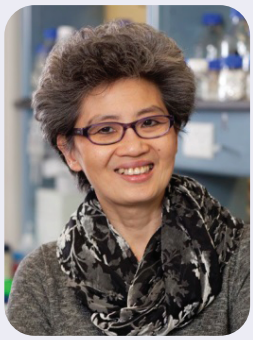
Joint CUHK-NTEC CRMO Newsletter
Issue 1: September 2014

Director's Message



Dear colleagues,

Welcome to the first newsletter from the CUHK-NTEC CRMO, established in June 2013 to serve as a bridge amongst relevant stakeholders engaged in clinical research including investigators, research personnel, sponsors, auditors, ethics board, regulatory agency, clinical research organizations, to name but a few.

The practice of medicine is complex and probabilistic. For the same disease, different people may have different presentations and similarly, for the same treatment, different people may have different responses. It is this heterogeneity that makes research extremely important to understand causes and consequences in order to give the right treatment to the right patient at the right time for the right outcome.

Observation, documentation, analysis, hypothesis formulation, experimental testing and ongoing evaluations are the essential steps in our pursuit of solutions to address unmet clinical needs. However, during these scientific inquiries, protection of the study subjects and data integrity with accountability and credibility is critically important. Amongst different types of research studies, interventional trials using potentially invasive methods, including but not limited to drugs, devices, procedures, for unlicensed indications, which may eventually change practice, are particularly subject to scrutiny.

During the last 3 decades, the CUHK-PWH partnership, supported by a network of hospitals and clinics in the NTEC, has provided enormous momentum in defining unmet clinical needs and innovating strategies through many research programs pertaining to basic, clinical, translational and improvement science. Apart from contributing to the international body of knowledge through publications, many of these programs have influenced clinical practice and health care policy for better patient care.

In 2006, 6 clinical research units at PWH were accredited by the China Food and Drug Administration (CFDA) subject to renewal every 3 years. In 2013, the PWH entered a 2-yearly cycle of external audit with clinical research as one of the areas for inspection. In December 2013, the CUHK-NTEC Clinical Research Management Committee (CRMC), chaired by Dr. CK Li, was established to put in place the organizational structure to further enhance the central support for the conduct of clinical research programs at the CUHK-NTEC hospitals and clinics. In June 2013, I had the privilege to be appointed by the CUHK Faculty to be first Director of the CRMO to implement the terms of reference set out by the CRMC.

In September 2013, Ms. Iris Chan, a CUHK Pharmacy graduate with extensive managerial experience in the field of clinical pharmacy and pharmaceutical industry, was appointed as the Managing Director of CRMO. Under her stewardship, the CRMO was open on the 8th floor of the Lui Che Woo Clinical Sciences Building at the PWH in November 2013. Since then, the CRMO has enriched the CRMO website (http://www.crmc.med.cuhk.edu.hk/CRMOService.aspx) and put in place a multidisciplinary team consisting of programmers, scientific officer, research coordinator, quality assurance officer and administrator to realize our vision of

"creating a safe environment for scientific and ethical conduct of clinical research for evaluation of safety, efficacy and acceptability of novel compounds and treatment strategies for advancement of health sciences and quality care"

Many readers of this newsletter are practicing physicians who are in a unique position to make a real difference to patient care by translating evidence to practice, identifying unmet needs and testing novel solutions. To potential sponsors, the CUHK-NTEC has excellent research facilities and capacity to become a strategic partner in your discovery programs. To this end, the CRMO is here to hear your voice and will strive to serve your needs to create a research environment which combines quality research and good clinical care.

Ahead of us are many challenges and opportunities in our common aspiration to make Hong Kong a hub of biomedical research and innovative care, against an increasingly competitive environment. By leveraging on our complementary strengths, we hope the CRMO will play a role in this changing landscape by bringing out the best of your research programs through multiple partnerships.

Through this regular CRMO newsletter, we shall keep you informed of the 'what, why, how' of our various activities and initiatives. We hope you will enjoy the read and sincerely look forward to your feedback and comments.

Juliana Chan

MBChB MD FHKAM FRCP
Chair Professor of Medicine and Therapeutics

Events

ICH-GCP Seminar

Thanks a lot for your support to the ICH-GCP seminar held on 3 Jul. We were overwhelmed by the responses with more than a hundred attendees. Dr. Benny Fok has walked us through the key spirits of ICH-GCP. Further training on various aspects of GCP and study planning will be launched. The training slides have been uploaded onto the CRMO website.

Online ICH-GCP Certification Examination

An online GCP certification examination was arranged between 24 Jul and 6 Aug for our doctors, nurses and research colleagues to demonstrate their proficiency in ICH-GCP.

A total of 191 colleagues have attempted the examination and 171 have passed. With a passing rate close to 90%, we are delighted to see that most of our colleagues are well-equipped with GCP knowledge and are capable of conducting clinical trials in compliance with international standards.

CRMO SOP Train-the-trainer Workshops in NTEC Hospitals

In order to align the standard of clinical research, CRMO harmonizes and develops a catalog of research-related SOPs. With effect from 1 April 2014, 18 SOPs are applicable to CUHK and all NTEC hospitals. With the support from HCE of all NTEC hospitals, SOP "Train-the-trainer" workshops have been conducted for all these hospitals to help our colleagues to familiarize with the keys of the SOPs. More than 300 doctors, nurses, allied health professionals and scientific personnel participated in the workshops and gave us many positive feedbacks.

Clinical Research Partnership and Collaboration

One of the key objectives of CRMO is to work closely with clinical research partners including pharmaceutical industries, biotechnology companies and contract research organizations (CROs). CRMO acts as consultant to enhance and facilitate clinical trial processes and serves as the access to suitable potential investigators.

Many visitors who are global/regional senior executives from these companies have visited us in the past few months to discuss on enhancing partnership and collaboration.

Via CRMO, several potential clinical study projects have been initiated for further discussion with Principal Investigators.

Highlight of Research Unit

There are lots of strong research units who have dedicated their effort in improving the quality of care of our patients. We take this platform to introduce them to you. We are glad to have CCTU to take the lead!

Comprehensive Cancer Trials Unit (CCTU), Department of Clinical Oncology, Faculty of Medicine

The Comprehensive Cancer Trials Unit (CCTU), currently headed by Prof Anthony Chan (Chairman) and Dr. Edwin Hui (Director), has been established since 2001. It focuses on research programs including basic science, translational and clinical research. Our research team comprises of Site Chairs, Principal and Co-investigators, Statistician, Research nurses, assistants and data entry clerks and they work closely together as a one stop comprehensive centre of research excellence in cancers of particular importance in Asia. We have consistently produced high impact publications, and the high quality clinical trials and translational research are practice-changing and internationally recognized. One recent example of impactful publication is the NCI-CTEP-supported multicenter phase II study using PXD 101 as an epigenetic therapy which has been published in the Journal of Clinical Oncology (J Clin Oncol. 2012 Sep 20;30(27):3361-7). We have been conducting Phase 1 clinical trials and the recently completed phase I trial of recombinant modified vaccinia ankara encoding Epstein-Barr viral tumor antigens in nasopharyngeal carcinoma patients has been published (Cancer Res. 2013 Mar 15;73(6):1676-88). The phase II efficacy study of the MVA-EL vaccine in NPC patients continued with the aim to establish the clinical benefit of the EBV vaccine in NPC patients with recurrent or metastatic disease. Our collaborator Cancer Research UK has started recruitment for their parallel phase II trial.

As the China Food & Drug Administration accredited site in Hong Kong, CCTU has conducted several CFDA studies. In collaboration with Profs. Dennis Lo, KW Lo and Nathalie Wong, three major theme-based research grants have been awarded. Locally, multiple grants have been obtained from the Research Grant Council's General Research Fund for conducting research focusing on areas of novel tumor response assessment, epigenetics, signal transduction and biomarkers.

CCTU will continue to initiate and lead cutting-edge research with the aim of benefiting current cancer patients and change future cancer disease paradigm.

Tips of the Day

Query 1:

If a study sponsor wants to change the content of the HA indemnity letter, what can he/she do?

The study sponsor needs to approach one of HA's nominated lawyers to vet and approve the proposed amendments. Before any negotiation of the proposed amendments comments, the study sponsor has to pay the nominated lawyers on account and it would be fully responsible for settling the lawyer's costs. ✓✓

Query 2:

Does the investigator need to apply for Clinical Trial Certificate (CTC) if the clinical trial involves registered drug in registered indication?

Referring to "Guidance Notes on the Application for Certificate for Clinical Trial/ Medicinal Test" issued by the Drug Office of Department of Health, trials involving drug registered/ not registered in Hong Kong are required to apply CTC. Details about application of CTC can be found from CRMO-SOP-003 and also the website of the Drug Office. ✓✓

Announcements

External Archival Service

Offsite document storage service provided by an international archival service provider is now available at CRMO at reasonable price. Relevant information including the price list, information slides and forms can be accessed via CRMO website. Prospective budget can be estimated upon request and please contact CRMO for more information.

New Procedures on Clinical Trial Certificate (CTC) application

With effect from 1 May 2014, new CTC application procedures are launched. For low risk clinical trial, simplified mechanism can be applied. New application forms, guidance notes, FAQs and workflow chart can be downloaded at the following website of the Drug Office. You may also contact CRMO if you would like to seek advice on applying CTC.

https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/clinicalTrial.html

Upcoming Event

CRMO is planning to host a one day ICH-GCP workshop in early 2015 for those who are new to clinical research and those who would like to learn more about ICH-GCP. This GCP training will be endorsed by Transcelerate Biopharma Inc., a non-profit organization which provides a platform for mutual recognition of study site qualifications and training. By using this platform, our GCP training will be recognized globally by various pharmaceutical companies including, Pfizer, Astra Zeneca, Lilly, GSK, Johnson & Johnson, Roche, Sanofi, etc. One would then be able to eliminate the hassle of attending different GCP trainings for each study sponsor. Details of the workshop will be available early 2015.

Calling for Submission

Pieces of writing for the sections of "Feature Article (Highlight of Research Unit/ GCP Sharing)" and "Tips of the Day" are welcomed. You can send your article and photos with your particulars (name, hospital, department, position and contact information) to us.

Contact us

Joint CUHK-NTEC Clinical Research Management Office (CRMO)

8/F, Lui Che Woo Clinical Sciences Building, Prince of Wales Hospital, 30-32 Ngan Shing Street, Shatin, Hong Kong

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