Highlights

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It’s that time of year again! One of CRC Sabah’s annual event is Sabah Research Day (SRD) 2018 which this year was organized by Sabah Women And Children Hospital (SWACH) CRC and was held on the 12th & 13th September 2018. The theme selected for this year was “Dive into High Quality Research - The Endless Possibilities”. Therefore, our plenary talks and forum were tailored to match the theme. In conjunction with SRD 2018, CRC SWACH invited the Director General of Health, YBhg Datuk DR Noor Hisham bin Abdullah to concurrently officiate the research day as well as CRC branch in SWACH.

We managed to draw participants from various disciplines across Sabah to join us in this event. We received over 150 candidates who registered for the research day and about 91 of them submitted abstracts to compete in research presentation competition. This year, we had strong support from Tawau, Sandakan and Keningau districts. There were interesting and fruitful plenary session by our invited speakers from various backgrounds. All the participants loved the plenary talks as they claimed that the talks have inspired them to venture into high quality studies which will give an impact to current practices in medicine as well as society.

One of the highlights of this event is research presentation. We received a wide range of interesting topics this year, ranging from various diseases and cases. After review from the scientific committee, 10 abstracts has been selected for oral presentation, 31 abstracts for poster presentation and 50 abstracts for case report competition. It was a tight match between presenters as most of the researches were of fine quality and well prepared to confidently defend their work when razor-sharp judges raised their questions.

Last but not least, our forum on “High Quality Research for a Better Tomorrow” by invited expertise has encouraged participants to ask questions and the speakers had so many useful information to share. We believe through this event, all the participants will find inspiration to embark on their own journey towards high quality research.
A Good Clinical Practice 2018 Workshop (Keningau edition) was held from 30th June to 2nd July 2018 at Bilik Mesyuarat Utama, Keningau Hospital. The aim of the course was to provide an opportunity for clinicians, medical officers, pharmacist, allied healthcare from Keningau Hospital and surrounding areas to receive training and a chance to be GCP certified via the GCP examination set by National Pharmaceutical Regulatory Authority (NPRA).

This workshop was an initiative by Director of Keningau Hospital, Dr. Ridwan Hashim and research coordinator Mr. Sivaraj Raman (Pharmacist) collaborating with CRC HQE II in organizing the event. There was a total of 28 full course participants and 1 resit participant. Throughout the 3-day workshop, there was a good mix of lectures by invited speakers as well as group activities to reinforce the materials taught during the workshop.

We had the privilege to hear from Dr. Ho Tze Ming, from the Medical Research Ethics Committee (MREC) on ethical considerations in clinical research, Dr. Daren Teoh, Oncologist from KPJ Sabah presented on responsibility as an investigator and his experience in handling clinical trial as principal investigator, Mr. Goh Tse Seng shared more information on sponsor’s responsibility and role in clinical trials and Ms. Nabila Shaffie from NPRA on regulations in clinical research. Besides these lectures, there were group activities conducted to reinforce the lecture materials, such as investigational product (IP) accountability, case report form (CRF) exercises, matching roles of different agencies involved in clinical research and online quiz.

Overall, we believe that it was exciting and productive training for all the participants attended this workshop. We were very satisfied with the GCP results, 80% of the participants passed with flying colors!
Basic Research Methodology (BRM) workshop was held from 30th June to 1st July 2018 (Saturday to Sunday) and Statistical Package for the Social Sciences (SPSS) workshop on Monday, 2nd July 2018 organised by Clinical Research Centre, Hospital Queen Elizabeth II. Both workshop attended by 23 participants from various backgrounds.

BRM is two-day program which includes 12 topics such as Generating Research Ideas, Literature Review & Introduction to Critical Appraisal, Research Proposal Development, NMRR Registration, Study Designs, Sampling Method, Measurement Tools & Data Collection Method, Descriptive Statistics, Ethics Consideration & Consent Taking, Questionnaires Development, Inferential Statistics and Sample Size Calculation. The speakers were Dr. Ain, Dr. Yen, Ms. Grazele, Dr. Emelyne, Dr. Teoh and Ms. Su Lan from CRC HQE II.

However, SPSS workshop includes hands-on exercises such as Introduction to SPSS & Types of variables, Data entry & import, Data screening & preparation, Descriptive statistics and Inferential statistics. The speakers were Ms. Sulan, Ms. Grazele and Dr. Teoh from CRC HQE II. Beside that throughout the program, participants were given step-by-step approach on how to use SPSS using lectures and demonstration by speakers. Overall, it was a successful event with good response from participants.
The Clinical Research Centre Network Meeting 2/2018 was held on 10th July 2018. The welcoming speech was given by Datuk Dr. Shahnaz the Deputy Director General, Research and Technical Support. There was also a farewell ceremony for Dato’ Dr. Amar Singh and Dr. Maria Lee HS for their retirement, Dr. Selvakumar Sivapuniam for his transfer from Kuantan to Selayang Hospital. The aim of the meeting was to discuss researches that were conducted in government Hospital. There was a total of 30 CRC managers who attended the meeting. Throughout the meeting, there were numerous good input to reinforce the research governance regarding the responsibility of Hospital Director in governing research, based on DG’s talking points at KPK Khas meeting.

Thus, a circular has been released to all hospitals in Malaysia. MRG grant application approved process which involved protocol review for scientific validity, ethic and grant by firstly JPPNIH and then ethics by MREC. The grant will then go through final review by MRG grant panel, hence, this is a mechanism to improve success of MRG application by CRC and hospital staff. The quality and review timeline will be done by Hospital Research Review Committee (HRRC) for a better process and engagement with principal investigators. Dr. Alan Khoo (Molecular Pathology Unit, Cancer Research Centre) presented a collaborative research with Institute of Medical Research (IMR) and research that conducted in Cancer Research Centre. Dr. Lily Wong (CRC HQE) agreed to come again and interested to have a collaboration project in the future. We all had the privilege to be taken for a tour around the Cheras Rehabilitation Hospital compound and visited Dr. Anwar Ibrahim rehab room.

By Sharon Shang
Clinical Epidemiology Workshop

I was fortunate enough to attend the clinical epidemiology workshop organized by CRC Hospital Sultanah Nur Zahirah, Kuala Terengganu on 23-25 July 2018. The workshop was conducted by two Utrecht University lecturers, Prof. Michiel L Bots and Assoc. Prof. Ilonca Vaartjes. It was an intensive 3-days course as the lecturers mentioned this workshop was meant to be a 3 months e-learning course or to be taught over one semester in a master program!

The lecturers classified clinical research into 4 main categories using the DEPTH model: Diagnosis research, Etiology research, Prognostics research and Therapeutic research. During the workshop, we scrutinized the unique study designs and interpretation of analysis for each types of DEPTH research. We were also taught on the concept of prevalence and incidence (we dived deeper into the concept of cumulative incidence and incidence density).

I love how the course was conducted: minimal lectures, instead with plentiful of hands-on reading and group discussion. The speakers probed us to think rather than providing us a straightforward answer to our queries. With this opportunity to interact with international lecturers, I have strengthened my knowledge on the concepts of clinical epidemiology and realized that there are so much that I do not know! Personally, I enjoyed the course very much!

-By Yang Su Lan-

ISR Onyx ONE crosses target of 20 randomized subjects, and end of enrolment.

We have crossed our site target of 20 randomized subjects in the Onyx ONE global study, even going above and beyond up to 22 subjects! Congratulations to everyone in the team for their dedication! Globally, recruitment ended on 27 Sep 2018 as the global target of 2000 subjects were enrolled. We will be continuing follow ups for our amazing patient volunteers in this study up to Oct 2020.

Keep up the good work, team!

-By Teoh E V-
Every year CRC HQE II takes effort to organize Evidence Based Medicine (EBM), this year it was held on the 1st to 3rd August 2018. It was also my first time attending this workshop and Prof. Dr. Liew Su May was our invited speaker from University of Malaya. It was a 3-days intensive workshop learning about PICO (Population, Intervention, Comparator, Outcome) principle, critical appraisal, literature searching, and more exciting group work in appraising clinical papers.

I have learned the skill Prof. Liew has shared in reading “forest plot”, rapid appraisal of paper, and the importance of applying evidence based medicine in improving the quality of healthcare. I admire Prof. Liew’s and other CRC colleague presenting skills, which inspire me to be like them in future. Beside that, I also had opportunity sharing our inputs and idea with team member from different backgrounds.

Overall, EBM workshop was exciting and fruitful for all of us!

-By SN Vimala-
On the 6th & 7th August 2018, Hospital Queen Elizabeth II Nursing Unit invited CRC team as speakers for their Nursing Research Methodology Workshop. This workshop aim to facilitate and guide the nurses to come up with their research projects. This is an initiative from the Nursing Unit with CRC team in nurturing research culture among HQE II nurses.

Introduction to Clinical Research (ICR) 2018 was organized by Clinical Research Centre, Hospital Queen Elizabeth II. It was held on 18th and 19th August 2018. A total of 23 participants from various hospitals joined the workshop. Among them were medical officers and allied health personnels from Hospital Queen Elizabeth, Hospital Queen Elizabeth II, Hospital Tawau, Hospital Pulau Pinang, Institut Kanser Negara, KKIA Tambunan, Hospital Kudat, Hospital Beaufort, Hospital Keningau and Hospital Tenom.

In that two-day programme, participants were given lectures and all topics compiled in hard copies which then distributed in a file for each of them. All topics included Introduction to Good Research Practice, Ethics of Research, Essential Elements of Research Protocol, Pubmed Research and Literature Review, Measurement Tools and Data Collection Methods, Sample Size Calculation, Study Design, Critical Appraisal, Basic Medical Statistics (Differential and Inferential Statistics), Project Management and NMRR. At the end of the workshop, all participants were given e-certificates and soft copies of lecture materials.

By Dr. Emelyne
This year, I am so fortunate that my abstract was selected for oral presentation at 23rd Malaysia – Singapore Nursing Conference 2018 held at Malacca historical state from 5th September to 7 September 2018. The conference organized by Nursing Division of Ministry of Health Malaysia with the theme “Soaring together: Corroborating Academic and Practice in Nurturing Excellent Nursing Care”.

Throughout the conference there were interesting plenary sessions by invited speakers from Malaysia, Singapore and Australia. I was also excited to see their nursing culture and development in nursing research. Plenary on “Soaring Nursing Together” by Prof. Dr. Rohani bt Arshad really opened our eyes as participant in Corroborating Academic and Practice between Malaysia and Singapore.

I also enjoyed listening free paper presentation with various nursing background from Malaysia and Singapore. I am so happy in sharing my paper on “Barrier’s in attending Cardiac Rehabilitation Programme Among discharged ACS patient at Sarawak Heart Centre” on that day. Finally, I am so grateful to have this opportunity and I look forward to do more in future!

-SN Vimala-

“I AM AWARE” CAMPAIGN

Clinical Research Malaysia (CRM) staff QEH II, opened an “I AM AWARE” booth in conjunction with Clinical Trials Day Malaysia on 15th September 2018. We managed to get 25 healthy volunteer registered and 3 healthy volunteers were recruited in MAVERIK Study.
National Conference for Clinical Research (NCCR) 2018 was held on 24th and 25th September in Hotel Istana, Kuala Lumpur. It was organized by National Clinical Research Centre (NCRC) and involved various delegates from all over Malaysia. Eight representatives from Hospital Queen Elizabeth II joined the conference (CRC QEH II - Dr. Yen Chia How, Pharmacist Miss Yang Su Lan, Dr. Emelyne, Dr. Syarifah Nurul Ain, Dr. Teoh Eu Vin, SN Vimala, SN Sharon) including Dr Liew Houng Bang (Cardiologist, Head of CRC HQE II) and Dr. Hj. Razak bin Tambi (Director, HQE II).

It started with Plenary 1 by Y.Bhg. Datuk Dr. Noor Hisham, Director General of Health with the talk of Digital Heatlh Transformation - Connected Healthcare. The conference was then launched by YB Dr Lee Boon Chye (Deputy Minister Of Health Malaysia) with this year’s theme “Patient - Centered Research : Digital Health”.

Many participants joined the case study posters and clinical research posters competition as well, not to forget to mention those that participated in oral presentation.

It was such a great experience for all of us as well as we got the chance to make new friends with various healthcare providers from all over Malaysia.

By Dr. Emelyne
The investigator dialogue 2018 with topic “Good Clinical Practice Monitoring, Auditing & Inspection” was organized by Clinical Research Malaysia (CRM) on the 26th October 2018. The objective of the workshop was for investigators to bring up issues and discussion regarding the Industrial Sponsored Researches (ISR) and to improve the quality of research. CRM team also shared the activities or ongoing projects under CRM. There were 80 investigators from different corners of Malaysia whom participated in this dialogue.

During the investigator dialogue, Ms. Jennifer Chung gave a talk about “Quality management overview - Common Good Clinical Practice Deficiencies Encountered at site”. This is a good topic for the investigator to understand more about the common mistake done by other sites, and this can help investigators to conduct better quality research.

Clinical Research Malaysia also invited the Medical Research Ethic Committee (MREC) President to give a talk with the topic “Audit and inspection - What you need to know”. During the meeting CRM team explained about CRM professional services agreement and other research services provided by CRM. In the last section of the dialogue, there were small group discussion about the characteristics of a good quality site. This was a great platform for all the investigators in Malaysia to understand and learn how to conduct the good quality of research.

By Yen CH

Dr. Liew HB with colleague at Investigator Dialogue
Quality management overview: common Good Clinical Practice Deficiencies Encountered at site:

<table>
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<th>No.</th>
<th>Common Issue</th>
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| 1.  | Delegation log: Late documentation of trial related duties  
|     | Study specific training not completed before delegation of trial.  
|     | Tasks performed by staff not delegated or authorized. |
| 2.  | Inform consent process: Delay in re-consenting  
|     | No documentation of consent process in source document  
|     | Research procedure done before inform consent process. |
| 3.  | Investigator product: For blinded trial, lack of delineation of roles and responsibility and lack of traceability in IP repackaging.  
|     | Lack of traceability in IP return/ destruction record.  
|     | Wrong IP provided to subject. |
| 4.  | Safety data Lack of documentation and assessment of adverse event (AE) by clinician  
|     | Unreported/ delay AE/ severe adverse event |
| 5.  | Regulatory compliance/ Institute review board (IRB)/ Good clinical practice (GCP) Protocol deviation were not submitted to IRB  
|     | Updated protocol- not being implemented  
|     | Global SUSAR- submission not being done periodically |

Document what is done as well as what is not done: What is not documented is not done.

Responsibility of Principal investigator:
The general responsible as a clinical investigator include ensuring that the clinical trial are conducted according to the signed investigator statement, the investigational plan, and applicable regulation: protecting the right, safety, and welfare of subjects under your care; and ensuring control of drugs under investigation [21 CFR 312.60]