Qualité

Clinical Research Coordinator Society (CRCS) Forum

A/Prof Sim Kang

The CRCS faculty, in collaboration with the Clinical Research Professional (CRP) committee, successfully ran the Combined CRCS-CRP forum on 23rd August 2013. Held at the CRC auditorium at the National University of Singapore (NUS), the educational forum attracted 200 interested participants from public institutions and private organisations. Dr Yeo Jing Ping (chairperson, CRP) and Ms Doreen Lim (chairperson, CRCS) delivered the welcome address by introducing their respective committee / faculty members, as well as shared pertinent updates from the CRP and CRCS communities respectively.

Each invited speaker came from a different stakeholder group in the clinical research community – namely a pharmaceutical company, an institutional review board (IRB) and a public institution. They shared useful insights from their experiences on the theme of "Ensuring Quality and Compliance in Your Research Venture".

Importance of Healthcare Compliance on the Clinical Trial Environment – the Pharma Perspective

~Dr Abdul Luheshi

Vice-President for Healthcare Compliance, Johnson & Johnson~

Dr Abdul Luheshi presented his case on why healthcare compliance was crucial for pharmaceutical companies. While most people understood the need for internal regulation, Dr Luheshi furthered the case for healthcare compliance as a means of value generation for the company. To achieve corporate compliance, the resources for monitoring and audit had to be strongly supported by competent leadership at the top of the hierarchy.

He cited the potential risks that could potentially undermine healthcare compliance in the clinical research framework, from site selection to the hiring of a Contract Research Organisation (CRO) to run studies. Concluding the presentation, he emphasised that good ethics made for good business, hence qualifying the value of healthcare compliance in the pharmaceutical industry.

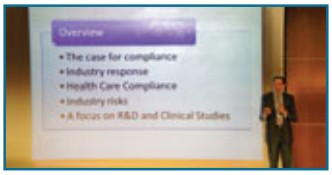
IRB Reviews and Your Research Protocol

~A/Prof Sim Kang, *Chairperson, Domain Specific Review Board (DSRB) Domain A, NHG Research & Development Office~*

A/Prof Sim Kang expounded on the role of an IRB in research compliance. He first debunked the myths of IRBs being an "ethical police" or a "rubber stamper" for research protocols, and introduced the seven elements constituting the systematic and coherent framework for determining ethical requirements in clinical research. While the material was didactic, A/Prof Sim's presentation was all but monotonous; the audience interest was buoyed by Jesse Gelsinger's story, a poignant video clip of the Tuskegee syphilis experiment,

Participants of the Forum

(from left) CRP Founder Ms Angie Sim, CRP Committee members Ms Ally Kim and Ms Katherine Lee, Dr Yeo Jing Ping, Ms Doreen Lim and CRP Committee member Ms Eung Jin Cho



Dr Abdul Luheshi

and A/Prof Sim's make-believe research study sporting numerous non-compliances to which he sought the audience's opinions. His presentation was informative and entertaining as well as thought-provoking. It gave forum participants a deeper understanding on how the IRB could value add in the protocol review process.

Best Practices in Clinical Research Quality and Compliance – the Institution's Perspective

~Ms Joanne Chio, *Head, Clinical Trials, Haematology-Oncology Research Group (HORG), Department of Haematology-Oncology, National University Cancer Institute, Singapore (NCIS), National University Hospital~*

Ms Joanne Chio's commitment to delivering clinical trials of respectable quality was evident from her reiterations on the importance of maintaining meticulous control over internal processes. While she shared useful pointers on how some common findings had been addressed, what came through most prominently was HORG's commitment to conducting routine internal audits as the first point of control in ensuring quality. Ms Chio introduced the HORG's "Audit Competition", which featured a demerit point system similar to that used for road traffic offences, as a quantitative indicator of the quality of ongoing clinical trials at HORG. It was precisely this "quality culture" that HORG had inculcated in its staff that had been pivotal allowing the team to ace audits and inspections from independent external parties.

Join the CRCS Mailing List!

The CRCS forum is organised three times a year, as an educational platform for sharing updates, learning best practices and exchanging new ideas across the clinical research community. Forum attendance is free of charge, and all in the clinical research community are strongly encouraged to participate in this learning experience.

If you have missed out on previous forums and would like to receive future updates from us, please drop us an email at researchcoord@nhg.com.sg, indicating your name, institution, job designation, contact and request to join the CRCS mailing list.

We look forward to seeing you at our next forum!

Ms Lim Boon Hwee
Senior Executive
Researchers' Training and Support (RTS)
Office of Human Research Protection Programme (OHRPP)
Research & Development Office
National Healthcare Group