GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION

GMS5108 Clinical Studies and Evaluation of Health Products

24 - 28 March 2025

WORKSHOP PROGRAMME

Learning Outcomes

At the end of this workshop, participants should be able to

- Describe the design and operational attributes of different phases of clinical trials
- Apply relevant regulatory guidelines to review clinical trial applications and marketing authorization applications of pharmaceutical products
- Explain basic principles of pharmacokinetic and statistical analyses as relevant to assessing benefit-risk ratio and regulatory decision-making for approval of pharmaceutical products.
- Explain the ethical, legal and regulatory aspects of design and conduct of clinical trials.
- Distinguish clinical trial design and operations between global clinical trials and domestic clinical trials.

Target Audience

Early to mid-career professionals: regulatory affairs professionals in pharmaceutical companies, healthcare professionals, academic researchers in lifesciences and regulators in national (health/drug) regulatory authorities.

Graduate Certificate in Health Products Regulation

GMS5108 Clinical Studies and Evaluation of Health Products

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Day 1 – 24 March 2025, Mon

Time	Topic	Speaker/ Organisation
8.30am	**Introduction to Graduate Certificate Workshop**	**Dr Rathi Saravanan** Lead Education Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.50am	**Workshop Briefing**	**Dr Uttara Soumyanarayanan** Senior Education Associate CoRE, Duke-NUS Medical School
9.00am	**Ice-breaker Activity** • Brightspace Familiarization • Introduction of team members • Goal setting	**Mr Osman Bin Mohamad** CoRE, Duke-NUS Medical School
9:25am	**Photo-taking Session: Faculty & Participants**	**Education Team**
Session 1: Introduction to Clinical Trials		
9.30am	**Overview of Clinical Trial Landscape** • Limitations of conventional RCTs • Novel Trial Designs • Clinical trial activities in ASEAN	**Dr Uttara Soumyanarayanan** CoRE
10.15am	**Tea Break**	

10.30am	**Ethical and Legal Aspects**
	• IRB and Ethical Oversight
	  ○ Responsibilities, Composition & Functions
	  ○ IRB workflow – submission and review
	  ○ Reporting to IRB
	• HPA/MA and HBRA Regulations
	  ○ Updates on Regulations
	  ○ Impact on Informed Consent
	  ○ Safety and noncompliance reporting
		Dr Yeo Jing Ping
		Senior Vice President
		Operational Excellence
		George Clinical

Session 2: Clinical Trial Design & Operations		
11.15am	**Clinical Trial Operations** • 5 project phases of clinical trials • Key functions and process in CTOs • The site Perspective & the Patient Perspective • Clinical Trials 2.0	**Dr Yeo Jing Ping** George Clinical
12.15pm	**Lunch**	
1.30pm	**Fundamentals of Multi-regional Clinical Trials** • ICH E17 Guideline for MRCT • Global drug development: Industry perspective • CTD and region-specific Information • Resolving conflicts between MRCT and domestic drug development	**Dr Yeo Jing Ping** George Clinical

2.30pm	**Case Discussion I** • Review Patient Information Sheet and Informed Consent Form to find deficiencies	**Expert Faculty: Dr Yeo Jing Ping** George Clinical
3.30pm	**Tea Break**	
3.45pm	**Case Discussion II** • Considerations for planning MRCTs	**Expert Faculty: Dr Yeo Jing Ping** George Clinical
5.30pm	**End of Day 1**	

Day 2 – 25 March, Tue

Time	Topic	Speaker/ Organisation
Session 3: Nonclinical and Clinical Development of Pharmaceutical Products		
8.30am	**Nonclinical Development of Pharmaceuticals** • Pharmacology & Pharmacokinetics • Toxicology studies • Safe starting dose & Safety Margins	**A/Prof Cynthia Sung** Adjunct Associate Professor Duke-NUS Medical School
9.30am	**Case Discussion III** • Interpreting nonclinical data • Significance for designing FIH studies	**Expert Faculty** A/Prof Cynthia Sung
10.30am	**Tea Break**	
10.45am	**Case Discussion III Continued**	
11.30am	**Oncology vs Non-Oncology Drug Development** • Clinical endpoints, surrogate markers • Trial Designs: Single arm studies, RCTs • Patient Stratification • Regulatory Approval Pathways • Case Examples	**Dr Catharine Bulik** Associate Director of Clinical Pharmacology Vertex Pharmaceuticals Former U.S. Food and Drug Administration (US FDA)
12.30pm	**Lunch**	

1.30pm	**Clinical Trials to Support Drug Development**
	• Basics of Clinical Trials
	  ○ Types of trial designs
	  ○ Blinding, randomization
	  ○ Sample size, patient population
	• Clinical Development of Pharmaceuticals
	  ○ Drug Discovery
	  ○ Preclinical Studies
	  ○ Phase 1 Safety and Dose escalation studies
	  ○ Phase 2 and Phase 3 Efficacy Studies
	  ○ Phase 4 post-marketing
	  ○ Conclusion
		A/Prof Danny Soon
		Chief Executive Officer
		Consortium for Clinical Research and Innovation Singapore (CRIS)
		
		Adjunct Associate Professor,
		Duke-NUS Medical School

2.30pm	**Practicum I: Phase 1 Trials** • Design of Phase 1 Clinical Trials • Identifying Dose-limiting toxicities • Documenting Clinical Trial Protocols	**Expert Faculty:** A/Prof Danny Soon
3.00pm	**Tea Break**	
4.30pm	**Practicum I continued**	
5.30pm	**End of Day 2**	

Day 3 – 26 March, Wed

	Topic	Speaker/ Organisation
8.30am	Individual and Group Readiness Assessments (IRA/GRA)	**CoRE Education Team**
Session 4: Clinical Trial Data Analysis & Regulatory Decision-Making		
9.30am	**Utility of PK/PD Across Different Clinical Trial Phases** • Dosing regimen • Time to steady state • Bioequivalence studies • Clinical Trial Simulations	**A/Prof Cynthia Sung** Duke-NUS Medical School
10.30am	**Practicum II: Phase 2 trials** • Analysis of safety and efficacy data of Phase 2a • Design criteria for Phase 2b trials	**Expert Faculty:** A/Prof Cynthia Sung
10.45am	**Tea Break**	
11.00am	**Practicum II continued**	
1.00pm	**Lunch**	
2.00pm	**Quality Management in Clinical Trials** • Introduction to Good Clinical Practices (GCP) • Standard Operating Procedures (SOPs) • Quality control (Monitoring) and Quality Assurance (Audit and Inspection) • Identifying and rectifying issues • Preparing for inspections	**Mr Eric Seow** Trainer Singapore Clinical Research Institution **Ms Tan Siew Hoon** Trainer Singapore Clinical Research Institution
3.00pm	**Statistical Principles for Clinical Trial Data Analysis** • Concepts for analysing trial data: p-value, CI, sample size, power • Coherence and validation of primary endpoints • Interim Analysis • Judgement – Clinical Relevance and alignment to practice guidelines • Case examples: Product Application Examples	**Dr Chan Sze Ling** Senior Research Fellow II, Health Services Research Centre SingHealth
4.15pm	**Tea Break**	
4.30pm	**HSA's regulatory framework for clinical trials** • Overview of HSA's regulatory approach • Key regulatory requirements for clinical trial applications • Regulatory considerations in clinical trial review	**Dr Alvin Chia** Regulatory Consultant Health Sciences Authority (HSA) Singapore
5.30pm	**End of Day 3**	

Day 4 – 27 March, Thur

	Topic	Speaker/ Organisation
8.30am	**Navigating the Regulatory Landscape: Overcoming Challenges in Early-Phase Clinical Trial Applications** • Successfully navigating early-phase interactions with regulators (e.g., pre-IND meetings and INTERACT). • CTA dossier structure and global regulatory components. • Dossier preparation for early-phase submissions: integrating CMC, clinical, and non-clinical aspects for a successful regulatory package. • CTA submission and approval processes in the US and some APAC regions.	**Mr Carlo Polo** Senior Director, Head of Regulatory Science Hummingbird Bioscience
9.30am	**Considerations in regulatory decision-making of MAA** • Linking nonclinical, early and late phase data • Benefit/Risk assessment • Statistical significance versus clinical relevance • Assessing efficacy and safety data • Inputs for Risk management plans & Labelling • Final regulatory decision-making incorporating CMC	**Dr Andrew Pengilley** Senior Medical Advisor, International Regulatory Branch, Therapeutic Goods Administration (Australia)
10.30am	**Tea Break**	
10.45am	**Safety data analysis and reporting in Clinical Trials** • Safety analysis plan • Common AE templates/tools • Severity, AEs, safety parameters measured • Analysis: Safety monitoring and reporting	**Dr Branka Stanic** Clinician Scientist, Postdoctoral Fellow Georgetown University
12.00pm	**Lunch**	
1.00pm	**Practicum III: Phase 3 design and data analysis** • Phase 3 trials: design, choosing endpoints, powering the trial • Phase 3 trials: Review of safety data • Regulatory decision-making	**Asst/Prof James Leong** Head Health Products & Regulatory Science CoRE, Duke-NUS Medical School
3.00pm	**Tea Break**	
3:15pm	**Practicum III continued**	
4.30pm	**Networking Activity**	**CoRE Education Team**
5.30pm	**End of Day 4**	

Day 5 – 28 March, Fri

	Topic	Speaker/ Organisation
8.30am	**End of the Module assessment (EOM)**	**CoRE Education Team**
9.30am	**Tea Break**	
9:45am	**Review of EOM Assessment**	**CoRE Education Team**
Session 5: Trends in Clinical Trials		
10.30am	**Innovations in Clinical Trial Design** • Novel therapeutics and Trial Designs • Embedding AI in clinical development • Regulatory Considerations	**Dr Yannis Jemiai** Chief Scientific Officer Cytel, Cambridge, MA
11.30pm	**Pharmacogenetics and Ethnicity** • Factors influencing drug metabolism, efficacy & safety • Potential for Pharmacogenomics (PGx) to reduce adverse drug responses (ADRs) • Challenges in navigating a regulatory pathway for implementation of PGx	**Dr Michael Winther** Senior Director, Target Discovery Engine Biosciences Pte Ltd
12.15pm	**Lunch**	
1:15pm	**Real-world Evidence (RWE) in Clinical Trials** • How does it complement RCTs? • Data sources • Analysis methods • Regulatory expectations	**Ms Lakshmi Sameera Dumpala** Associate Principal, Real World and Medical Affairs Solution Lead IQVIA
2:15pm	**Patient Engagement in Clinical Trials** • Benefits of PE • Methods of engagement • Patient-Centric Design • Ethics of PE • Communication and Education • Patient Advocacy and Support • Singapore Landscape	**Dr Ritu Jain** Senior Lecturer School of Humanities, NTU Lee Kong Chian School of Medicine Co-chair of Consumer Panel, ACE **Ms Ai Ling Sim Devadas** Deputy Director, Office of Patient Engagement (OPEN) l Patient Advocate Lee Kong Chian School of Medicine
3.15pm	**Tea Break**	
3:30pm	**Reflection and Peer Sharing**	**Mr Osman Bin Mohamad** CoRE
4.30pm	**Workshop conclusion**	**Prof Silke Vogel** Deputy Director, Centre of Regulatory Excellence Senior Associate Dean, Office of Education, Duke-NUS Medical School
5.00pm	**End of GMS5108 Workshop**	