GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5108 Clinical Studies and Evaluation of Health Products

18 – 19 & 22 – 24 February 2027

Venue: Whitespace (Academia, SGH),

White Space Room (Level 2), Academia, 20 College Rd, Singapore 169856

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 life sciences 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 – 18 February 2027, Thursday

Time	Topic	Speaker/ Organisation
8.30am	**Introduction to Graduate Certificate Workshop**	**Dr Rathi Saravanan** Lead Education Associate Lead, Graduate Certificate Programme Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.50am	**Ice-breaker Activity** • Brightspace Familiarization • Introduction of team members • Goal setting	**Dr Rathi Saravanan** Lead Education Associate CoRE
9.15am	**Workshop Briefing**	**Dr Uttara Soumyanarayanan** Senior Education Associate CoRE, Duke-NUS Medical School
Session 1: Introduction to Clinical Trials		
9.30am	**Introduction to Clinical Trials** • Important Guidelines- ICH E6, E17 • Introduction to GCP • Safety Guidelines	**Dr Uttara Soumyanarayanan** CoRE, Duke-NUS Medical School
10.15am	**Tea Break**	
10.30am	**Clinical Trials to Support Drug Development** • Basics of Clinical Trials ○ Types of trial designs ○ Sample size, patient population • Clinical Development of Pharmaceuticals ○ Preclinical Studies ○ Phase 1 - 4 Trials & Objectives	**A/Prof Danny Soon** Chief Executive Officer Consortium for Clinical Research and Innovation Singapore (CRIS) Adjunct Associate Professor, Duke-NUS Medical School
12.00pm	**Lunch**	
Session 2: Clinical Trial Design & Operations		
1.00pm	**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	**TBC**
2.00pm	**Nonclinical Development of Pharmaceuticals** • Pharmacology & Pharmacokinetics • Toxicology studies • Safe starting dose & Safety Margins	**TBC**
3.15pm	**Tea Break**	
3.30pm	**Case Discussion I** • Interpreting nonclinical data • Significance for designing FIH studies	
4.15pm	**Networking Session**	**Dr Rathi Saravanan** CoRE, Duke-NUS Medical School
5.30pm	**End of Day 1**	

Day 2 – 19 February 2027, Friday

Time	Topic	Speaker/ Organisation
Session 3: Clinical Development of Pharmaceutical Products		
8.30am	**Principles of Oncology Drug Development** • Clinical endpoints, surrogate markers • Trial Designs: Single arm studies, RCTs • Patient Stratification • Regulatory Approval Pathways • Case Examples	**TBC**
9.30am	**Practicum I: Phase 1 Trials** • Design of Phase 1 Clinical Trials • Identifying Dose-limiting toxicities • Documenting Clinical Trial Protocols	**Expert Faculty:** **CoRE Education Team**
10.30am	**Tea Break**	
10.45am	**Practicum I: Phase 1 Trials** Continued	
12.30pm	**Lunch**	

1.30pm	**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
		Vice President, Clinical Operations & Head, Asia Pacific, Precision for Medicine, Singapore

2.30pm	**Case Discussion I** Review Patient Information Sheet and Informed Consent Form to find deficiencies	**Expert Faculty: Dr Yeo Jing Ping** Precision for Medicine
3.30pm	**Tea Break**	
3.45pm	**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** Precision for Medicine
5.00pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 2**	

Day 3 – 22 February 2027, Mon

	Topic	Speaker/ Organisation
8.30am	Individual and Group Readiness Assessments (IRA/GRA)	**CoRE Education Team**
Session 4: Clinical Trial Data Analysis & Regulatory Decision-Making		
9.30pm	**Utility of PK/PD Across Different Clinical Trial Phases** • Dosing regimen • Time to steady state • Bioequivalence studies • Clinical Trial Simulations	**TBC**
10.30am	**Tea Break**	
10.45am	**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	**TBC**
12.00pm	**Lunch**	
1.00pm	**Phase 2 Trials: Refresher**	**Dr Uttara Soumyanarayanan** CoRE, Duke-NUS Medical School
1.15pm	**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
3.45pm	**Tea Break**	
4.00pm	**Biostatistics for Evaluation of Clinical Trial Data** • 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	**TBC**
5.00pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 3**	

Day 4 – 23 February, Tue

	Topic	Speaker/ Organisation
8.30am	**Safety data analysis and reporting in Clinical Trials** • Safety analysis plan • Common AE templates/tools • Signal detection and benefit–risk assessment during development • Regulatory expectations for clinical trial safety reporting	**TBC**
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	**TBC**
10.30am	**Tea Break**	
10.45am	**TBD**	
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**	
4:00pm	**Rethinking Clinical Trials: Flexibility, Patient Centricity, and Innovation** • Limitations of conventional RCTs • Adaptive Trials • Pragmatic Trials • Decentralised Trials	**Dr Uttara Soumyanarayanan** CoRE
5.00pm	**Debrief and Announcements**	**CoRE Education Team**
5.30pm	**End of Day 4**	

Day 5 – 24 February 2027, Wed

	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	**TBC**
11.30am	**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** Precision for Medicine
12.30pm	**Lunch**	
1:30pm	**Case Discussion III**	**Expert Faculty: Dr Yeo Jing Ping** Precision for Medicine
2:30pm	**Panel Session** ***The Future of Clinical Trials: Innovations, Emerging Trends and Opportunities***	**Moderated by: Dr Yeo Jing Ping** **Panelists:**
3.15pm	**Tea Break**	
3:30pm	**Reflection and Peer Sharing**	**Dr Rathi Saravanan** CoRE
4.30pm	**Workshop conclusion**	**Asst/Prof James Leong** Head Health Products & Regulatory Science CoRE, Duke-NUS Medical School
5.00pm	**End of GMS5108 Workshop**	