REGULATIONS FOR THE DEGREE OF MASTER OF CLINICAL RESEARCH AND PRODUCT DEVELOPMENT (MCRPD)

These regulations apply to candidates admitted to the Master of Clinical Research and Product Development in the academic year 2026-27 and thereafter.

*(*See also *General Regulations and Regulations for Taught Postgraduate Curricula)*

MCRPD.1 Definition

The degree of Master of Clinical Research and Product Development (MCRPD) is a postgraduate degree awarded for the satisfactory completion of the curriculum of one academic year of full-time study or two academic years of part-time study in the Department of Medicine, Li Ka Shing Faculty of Medicine. Any publication based on work approved for a higher degree should contain a reference to the effect that the work was submitted to The University of Hong Kong for the award of the degree.

MCRPD.2 Admission requirements

To be eligible for admission to the curriculum leading to the degree of Master of Clinical Research and Product Development, a candidate shall:

(a) comply with the General Regulations and the Regulations for Taught Postgraduate Curricula; and
(b) hold a Bachelor's degree of this University, or a qualification of equivalent standard from this University or another comparable institution accepted for this purpose. Preference will be given to candidates who have graduated from healthcare-related programmes; and
(c) satisfy the examiners in a qualifying examination, if required.

MCRPD.3 Qualifying examination

(a) A qualifying examination may be set to test the candidate's formal academic ability or his/her ability to follow the courses of study prescribed. It shall consist of one or more written papers or their equivalent and may include a project report; and
(b) A candidate who is required to satisfy the examiners in a qualifying examination shall not be permitted to register until he/she has satisfied the examiners in the examination.

MCRPD.4 Award of degree

To be eligible for the award of the degree of Master of Clinical Research and Product Development, a candidate shall:

(a) comply with the General Regulations;
(b) comply with the Regulations for Taught Postgraduate Curricula; and
(c) complete the curriculum and satisfy the examiners in accordance with the regulations set out below.

MCRPD.5 Advanced standing

Advanced standing may be granted to a candidate who has successfully completed equivalent courses within this University or at another comparable institution, subject to the following conditions:

(a) such course(s) should be completed no more than 5 years prior to the candidate's commencement of the Master of Clinical Research and Product Development curriculum; and
(b) such course(s) should be appropriate for the Master of Clinical Research and Product Development courses that the candidate has applied for; and
(c) advanced standing for up to 12 credits may be granted.

Application for advanced standing shall normally be made prior to the candidate's admission to the curriculum. Academic transcript and relevant course syllabus should be submitted. All applications are considered on a case-by-case basis by the Board of Studies and shall be approved by the Faculty Board.

MCRPD.6 Period of study

The curriculum shall normally extend over one academic year of full-time study, or two academic years of part-time study. Candidates shall not be permitted to extend their studies beyond the maximum period of registration of two academic years of full-time study, or four academic years of part-time study, unless otherwise permitted or required by the Faculty Board.

MCRPD.7 Completion of curriculum

To complete the curriculum, a candidate shall:

(a) satisfy the requirements prescribed in TPG6 of the Regulations for Taught Postgraduate Curricula;
(b) take no less than 66 credits in the manner specified in these regulations and the syllabus, and follow the instructions in the syllabus prescribed for the courses and complete satisfactorily all required written, practical and/or clinical work;
(c) satisfy the examiners in the courses by continuous assessments and/or by written examinations; and
(d) complete a satisfactory capstone report on an approved project.

A candidate who fails to fulfil the requirements within the prescribed maximum period of study shall be recommended for discontinuation under the provision of General Regulation G12, except that a candidate who is unable because of illness or circumstances beyond his/her control to complete the requirements within the prescribed maximum period of study, may apply for permission to extend his/her period of studies.

MCRPD.8 Assessment

(a) A candidate who has failed to satisfy the examiners in a course in the first attempt may be permitted:
    - to attend a re-examination; or
    - to re-submit the failed assessment(s) without having to repeat the course; or
    - to repeat the course and the prescribed assessment(s)/examination(s).
(b) A candidate who has failed to satisfy the examiners in the capstone report, but has satisfactorily completed the prescribed work, may be permitted to re-submit the report within a specific period of time.
(c) A candidate who has failed to satisfy the examiners in the second attempt in any course(s), capstone report, or exceeded the prescribed maximum period of study shall be recommended for discontinuation of studies under the provisions of General Regulation G12.
(d) Candidates shall not be permitted to repeat a course for which they have received a passing grade for the purpose of upgrading.

MCRPD.9 Grading system

a) Individual courses (except the capstone) will be graded according to the following grading system:

Grade	Standard	Grade Point
A+	Excellent	4.3
A		4.0
A		3.7
B+	Good	3.3
B		3.0
B-		2.7
C+	Satisfactory	2.3
C		2.0
C-		1.7
D+	Pass	1.3
D		1.0
F	Fail	0

b) The capstone will be graded according to the "Distinction", "Pass" and "Fail" grading system.

c) On successful completion of the curriculum, a candidate who has shown exceptional merit may be awarded a distinction as determined by the Board of Examiners for the degree which shall be recorded in the candidates' transcript.

SYLLABUS FOR THE DEGREE OF MASTER OF CLINICAL RESEARCH AND PRODUCT DEVELOPMENT (MCRPD)

These syllabuses apply to candidates admitted to the Master of Clinical Research and Product Development in the academic year 2026-27 and thereafter.

The Master of Clinical Research and Product Development (MCRPD) curriculum requires the satisfactory completion of 8 compulsory courses and a capstone project, with a total of 66 credits.

Course	Credits
Area I. Clinical Therapeutics	
CRPD6001 Clinical Therapeutics I	9
CRPD6002 Clinical Therapeutics II	6
CRPD6003 Clinical Therapeutics III	6
Area II. Clinical Research Management	
CRPD6004 Fundamentals of Clinical Research	6
CRPD6005 Clinical Trial Essentials	6
CRPD6006 Medicine in the Real World	6
Area III. Healthcare Product Development	
CRPD6007 Product Development and Project Management	6
CRPD6008 Product Commercialization and Marketing	6
Capstone	
CRPD6009 Capstone Project	15
Total	**66**

The mode of assessment for non-capstone courses comprises of continuous assessment (40%-100%) and written examinations (0%-60%). Continuous assessment comprises of class/online tests, in-class performance, and various types of assignments, such as written report, oral presentation, and individual/group projects. Capstone assessment will be based on continuous evaluation of students' output at various project stages, including the final capstone report.

Course Description

Area I: Clinical Therapeutics (Total 21 credits)

Course and Description	Covered Topics
CRPD6001 Clinical Therapeutics I (9 credits) This course introduces the therapeutic aspect of various chronic medical diseases that are commonly investigated in clinical trials.	• Cardiovascular diseases, such as coronary artery disease, atrial fibrillation, heart failure and valvular heart disease. • Kidney diseases, such as acute kidney injury, chronic kidney disease, IgA nephropathy and polycystic kidney disease. • Metabolic diseases, such as Type 2 diabetes, obesity and dyslipidaemia. • Neurological and geriatric diseases, such as Alzheimer's disease, Parkinson's disease, epilepsy, acute stroke. • Gastrointestinal / liver diseases, such as inflammatory bowel disease, irritable bowel syndrome, hepatitis B, metabolic-associated fatty liver disease. • Clinical trial aspect of rare diseases

CRPD6002 Clinical Therapeutics II (6 credits) This course introduces the therapeutic aspect of various oncological and hematological diseases that are commonly investigated in clinical trials.	• Common cancer, such as breast cancer, lung cancer, colorectal cancer, liver cancer, prostate cancer, lymphoma and leukemia. • Commonly investigated drug molecules, such as immune checkpoint inhibitors, tyrosine kinase inhibitors, monoclonal antibodies and PARP inhibitors. • Specific genetic mutations relevant to oncology therapeutics, such as PD-1/PD-L1 pathways, EGFR mutation in lung cancer and HER2 pathways in breast cancer.
CRPD6003 Clinical Therapeutics III (6 credits) This course introduces the therapeutic aspect of various immunological, dermatological, rheumatological, respiratory and infectious diseases that are commonly investigated in clinical trials.	• Immunological, dermatological and rheumatological diseases, such as atopic dermatitis, primary immunodeficiencies, psoriasis, rheumatoid arthritis, systemic lupus erythematosus. • Respiratory diseases, such as asthma, chronic obstructive pulmonary disease, pulmonary fibrosis. • Infectious diseases (e.g. HIV, influenza, COVID-19) and vaccine development (e.g. influenza, respiratory syncytial virus, cytomegalovirus, norovirus). • Discuss trials in vulnerable populations (e.g. paediatrics, elderly, obstetrics, custodial)

Area II: Clinical Research Management (Total 18 credits)

Course and Description	Covered Topics
CRPD6004 Fundamentals of Clinical Research (6 credits) This course equips students with a comprehensive understanding of fundamental concepts and methods in clinical research.	• Clinical research methodology, such as indications, pros and cons of different study designs (e.g. randomized controlled trials, cohort studies, case-control studies, meta-analysis), bias and confounding, ethical considerations in clinical research, and the development of a research protocol. • Biostatistics, such as basic statistical concepts, basic statistical tests (e.g. t-test, chi-square and regression analysis). • Basic epidemiological principles, such as incidence, prevalence, odds ratio and attributable risks, distinguishing correlation and causation. • Health economics, such as cost-effectiveness analysis, characteristics of healthcare markets, healthcare demand and supply, pharmaceutical economics.
CRPD6005 Clinical Trial Essentials (6 credits) This course highlights the key aspects of clinical trial, from study design and regulatory approval to data management and quality assurance. Students will develop the knowledge and skills needed to navigate the complexities of clinical trial conduct and ensure the	• Phases of clinical trials (Phases I-IV) • Clinical trial design and pitfalls • Inclusion and exclusion criteria and informed consent • Regulatory and ethical approval for clinical trials • Good Clinical Practice (GCP) • Management of clinical trial logistics • Pharmacovigilance on adverse events (AE), serious adverse events (SAE) and suspected unexpected adverse events (SUSAR) • Quality assurance and management system

successful execution of research studies.	• Data management, such as case report forms and other data collection tools, techniques for accurate and reliable data collection. • Investigation medical product (IMP) certification
CRPD6006 Medicine in the Real World (6 credits) This course introduces the latest advancements in modern medical technology, encouraging students to effectively apply their skills to drive progress in clinical research and healthcare product development.	• Evidence-based medicine, such as levels of evidence, PICO framework, key databases and resources (e.g. PubMed and Cochrane Library). • Interpretation and appraisal of publications, and distinguishing high-quality vs low-quality evidence. • Application of evidence to clinical practice, such as clinical guidelines. • Digital health and technology, such as the implementation of digital medicine, telemedicine and telehealth, biosensors and wearables. • Impact of artificial intelligence (AI) on healthcare and drug development • Multiple OMICs technological platforms • Biomarkers in clinical research

Area III: Healthcare Product Development (Total 12 credits)

Course and Description	Covered Topics
CRPD6007 Product Development and Project Management (6 credits) This course introduces the cutting-edge clinical and medical product development, as well as project management fundamentals, enabling students to gain the skills and expertise required to lead successful product development initiatives in the healthcare industry. The utilization of biomedical engineering technologies in advancing healthcare settings will also be discussed.	• Pharmacology on new drug compounds, such as small molecules, biologics, cell therapies (e.g. CAR-T), gene therapies (e.g. CRISPR gene editing, RNA-based therapies, peptide drugs and nanomedicines). • Processes involved in early drug development, such as *in vitro* studies, *in vivo* studies, chemical and manufacturing standards, IND application to regulatory authorities. • Biomaterials (properties and types), medical and assistive devices (e.g. diagnostic, therapeutic and rehabilitative), and advanced imaging technologies. • Bioequivalence studies and its role in generic drug development. • Project management and operations, such as site selection, recruitment, budgeting, monitoring, timeline management.
CRPD6008 Product Commercialization and Marketing (6 credits) This course provides a comprehensive overview of strategic product commercialization in the healthcare industry. Students will develop the expertise needed to successfully navigate the commercialization journey, from concept to market launch, in the dynamic healthcare landscape.	• Entrepreneurship, such as business models, platform-based vs. product-based, role of venture capitalists and angel investors. • Technology transfer, such as the types of licensing agreements. • Intellectual property management (e.g. patents, trademarks, copyrights) and process of patent filing. • Regulatory approval for drug and medical devices, regulatory compliance for supplements and other health products. • Supply chain management, market analysis and strategy, and business development.

CRPD6009 Capstone Project (15 credits)

The capstone is a core component of the programme, encompassing 300 learning hours. Under the guidance of *Capstone Advisors*, students will undertake a capstone project that demonstrate their acquired skills and competencies in clinical research management and healthcare product development. The project should be completed within one semester.

Before beginning the projects, students will be offered an introductory session that highlights real-world scenarios related to clinical trials, product development and/or commercialization. By leveraging HKUMed's extensive collaborative network, they may have the chance to engage in various experiential learning activities in clinical research platform, such as the Clinical Trials Centres at HKU and HKU-Shenzhen Hospital, as well as the Greater Bay Area International Clinical Trial Institute (GBAICTI). These activities may include site visits, talks by invited experts, and practical demonstrations that cover the full spectrum of clinical trial management.

Participation in these experiential learning components allow students to enrich their understanding of real-world settings, observe the comprehensive processes involved in clinical research, and inspire their capstone project. Students are required to select a topic of interest for investigation and produce a capstone report, which may take one of the following forms:

1) drafting standard operating procedures (SOPs) for different aspects of a clinical trial; or
2) developing a risk management plan for clinical trials on how to identify, assess and mitigate risks; or
3) making proposals on product commercialization; or
4) a review dissertation on emerging and important areas of clinical research (e.g. artificial intelligence, telemedicine, digital tools, role of genetics) and clinical trials (e.g. cellular therapy, gene editing therapy, basket or umbrella trials).

The practical skills and knowledge gained from these experiential learning activities and the capstone project will equip students to become competitive candidates for careers in clinical trial/research, pharmaceutical companies, and regulatory agencies etc.