



GMDP ACADEMY OFFERINGS

2024

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Professional Certification in Medicines Development (CMD) - In Partnership with King's College London

Program Overview

This program is a unique partnership between academia, industry, and professional associations to foster competencies and improve medical affairs and medicines development performance. It is anchored by a strategic collaboration with King's College London, one of the world's leading research and teaching universities in London's heart.

The Certification in Medicines Development is ideal if:

- You are currently working in or looking to transition into Medicines Development
- You want to gain invaluable knowledge of Medicines Development and learn from leading global industry experts.
- You are a biomedical professional seeking to increase your visibility at your company.

Students completing the six modules and the end-of-program assessment will receive their Certification in Medicines Development (CMD) from GMDP Academy and King's College London and be authorized to use the post-nominal letters CMD.

The program is ten months long, from January through November every year. Students are expected to complete six modules that are six weeks long each, plus the end-of-program assessment.

Students can expect to spend 5 - 12 hours per week between the various activities.

Tuition Costs: \$4900 - \$9800 [See the Tuition Rate Sheet for more information](#)

Operational Dates

January 2024 - November 2024

Modules

- [Fundamentals in Medicines Development](#)
- [Medical Affairs and Health Economics](#)
- [Drug Discovery, Exploratory and Confirmatory Development](#)
- [Clinical Trials: From Concept to Clinical Study Report](#)
- [Regulatory Affairs, Drug Safety and Pharmacovigilance](#)
- [Medical Affairs as a Strategic Business Partner](#)

All modules available a la carte

To apply for one or more individual modules for the 2024 cohort, please visit: <https://info.gmdpacademy.org/gmdpapplication>

Individual Modules

MODULE 1: Fundamentals in Medicines Development

Program Overview

This module will take you through the fundamentals of clinical pharmacology, health economics, exploratory and confirmatory clinical development and clinical research, regulations, and long-term safety, including the emerging role of patients and contributions of the Medical Affairs function in these arenas.

Dates – Time Commitment – Tuition Costs

2024: Jan 15 to Feb 25	5-12 hours per week	\$2500
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Learning Outcomes

- Describe the drug development process using a Target Product Profile (TPP) and identify key factors and decision points critical to meeting stakeholder expectations.
- Describe the practical applications of pharmacokinetics and pharmacodynamics and the principles of clinical pharmacology.
- Describe how genetic factors can influence pharmacologic and toxic reactions and the molecular and cellular basis of these reactions in drug development and response.
- Explain the principles of translational research, including the use of statistics in medicines development.
- Conclude the importance of patients in drug development.
- Discuss the development of medicines regulation and the role of competent authorities in ensuring safety.
- Outline the principles of drug safety and risk management.
- Justify medical marketing and health economics principles, including the fundamentals of value in healthcare, Evidence-Based Medicine, Patient Reported Outcomes, and pharmacoeconomic metrics.

- Justify the importance of Medical Affairs in ensuring patients' availability and proper use of medicines through interaction with external stakeholders.

MODULE 2: Medical Affairs and Health Economics

Program Overview

This module will focus on how Medical Affairs functions as an effective interface with external stakeholders to ensure the right medicines are available for patient access and proper use. You will explore the processes involved in the evidence, data generation, health economics and commercialization and the application of digital technologies to ensure the candidate compound meets the desired profile to achieve regulatory approval and rapid entry into the healthcare system across countries.

Dates – Time Commitment – Tuition Costs

2024: Feb 26 to April 7	5-12 hours per week	\$2500
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Learning Outcomes

- Summarize the principles of medical/marketing and the role of Medical Affairs.
- Understand the processes of development and review of product information to ensure compliance with ethical, legal and regulatory principles about Good Promotional Practices and marketing activities.
- Appraise the contributions of the various medical affairs-related functions (medical information, medical communication and education, medical service liaisons, external affairs, strategic alliances, etc.) to successful business conduct within the organization.
- Understand the role of Medical Affairs in the life-cycle management of medicines (with clinical, regulatory and marketing), different types of data generation and the role of the medical affairs function.
- Outline the principles and practical applications of health economics and patient-reported outcomes, Health Technology Assessment and value generation and communication.
- Discuss the role of generics and biosimilars.
- Describe the emerging use of digital technologies in Medicines Development.

MODULE 3: Drug Discovery, Exploratory and Confirmatory Development

Program Overview

In this module, the scientific approach of drug discovery, biopharmaceutical formulation and non-clinical safety evaluation, and the early and confirmatory human trials of drugs and vaccines are covered. The discussion of the statistical assessment of the results and their contribution to the principles of evidence-based medicine completes the program.

Dates – Time Commitment – Tuition Costs

2024: April 8 to May 19	5-12 hours per week	\$2500
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Learning Outcomes

- Appraise the principles of rational design of chemical and biological drugs.
- Outline the steps in the non-clinical toxicological pharmaceutical development of a drug substance and the final product (including chemical and biological compounds).
- Describe the planning of clinical trial supplies (active or placebo).
- Outline the design of clinical trials, including legal, regulatory, ethical and practical aspects.
- Outline the specific principles of vaccine development.
- Describe the influence of genetic factors in drug development and drug response.
- Outline the exploratory development program: dose finding/proof of concept studies and their impact on the overall drug development plan.
- Outline the key operational and strategic issues in the Confirmatory Development Plan.
- Analyze and compare the principles and applications of statistics in clinical trials.
- Understand the importance of study design for conducting clinical trials.
- Communicate meaningfully with statisticians in project teams to ensure the aims of a trial are met.
- Understand the vital statistical issues when reading journal papers.
- Outline the principles of Evidence-Based Medicine and their relevance to drug development.

MODULE 4: Clinical Trials: From Concept to Clinical Study Report

Program Overview

This module will teach you how to conduct a quality clinical trial. This module will examine ethics, subject protections, quality management, and governance. You will also learn the procedures supporting good data collection and management, and budgeting practices. We will conclude by discussing issues related to clinical trial failures and the latest decentralized trial approaches.

Dates – Time Commitment – Tuition Costs

2024: May 20 to June 30	5-12 hours per week	\$2500
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Learning Outcomes

- Summarize the key documents related to the ethical conduct of clinical trials
- Outline the Investigators Brochure sections and describe its use, approval and distribution
- Revise the principles and practical relevance of ethical issues in biomedical research and the legal and ethical provision for the protection of clinical trial subjects
- Identify the key issues involved in the conduct of a clinical study including investigator and site selection, site management and conflict resolution
- Describe the procedures for clinical trial data collection and data management to ensure optimal quality data and outline the various quality management issues in clinical trials
- Outline a study level feasibility plan and describe the structure of a study budget
- Outline the various quality management issues in clinical trials
- Discuss the collection, evaluation and reporting of adverse event data in clinical trials
- Explain the role of the DSMB and other governance committees during the study conduct
- Discuss the evaluation and interpretation of clinical trials result.

MODULE 5: Regulatory Affairs, Drug Safety and Pharmacovigilance

Program Overview

This module will focus on the regulatory framework of medicines and medical devices development and approval in the US, EU, and emerging economies. The module will also cover global initiatives for harmonization (e.g., ICH) and highlight some key topics of interest (e.g., specialized regulatory procedures) and their role in the overall regulatory strategy. Risk management and safety reporting will be evaluated from the vantage point of a medicine's life cycle.

Dates – Time Commitment – Tuition Costs

2024: July 1 to Aug 11	5-12 hours per week	\$2500
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Learning Outcomes

- Categorize the general principles of medicines and device regulation and the regulatory process in the USA, Europe, and the rest of the world.
- Compare the role of national agencies and international bodies, such as the International Conference on Harmonization in medicines regulation
- Justify the impact of medicines legislative requirements on regulatory activities within a pharmaceutical company and its impact in planning and reviewing the product strategy
- Compare and contrast medical device regulation and drug regulations
- Value the role of pharmacoepidemiology and risk management in the lifecycle management of a medicine
- Appraise adverse events/adverse drug reactions in terms of severity and then describe the safety reporting requirements pre and post-approval
- Calculate and interpret measures of risk
- Evaluate the ongoing management of drug safety issues pre and post-approval (including risk management plans, periodic safety update reports, and post-authorization safety studies) and the ongoing benefit/risk assessment throughout the lifecycle of a medicine
- Evaluate the factors influencing medication safety from the perspective of each stakeholder
- Devise a global regulatory strategy to maximize the probability of successfully gaining regulatory agency approval of a new pharmaceutical
- Explain the conditions for involving patients in medicines development.

MODULE 6: Medical Affairs as a Strategic Business Partner

Program Overview

This module will cover the new role of Medical Affairs professionals as a strategic pillar in the pharmaceutical business. You will learn the ethics needed working in multidisciplinary clinical research or therapeutic teams, the role of patients and professional organizations in health care, how to address and improve organizational performance, the role of medical affairs in medical education, the importance of quality management, the value of strategic alliances and how to critically review a clinical research paper.

Dates – Time Commitment – Tuition Costs

2024: Sept 2 to Oct 13	5-12 hours per week	\$2500
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Learning Outcomes

- Understand the new role of MA professionals as strategic pillars in pharmaceutical business: purpose and career path.
- Describe ethical issues and ongoing tensions between the need for financial incentives for clinical research and medicines development and the global need for affordable medicines.
- Describe principles of professionalism, assessment of competence, and identity formation, to guide the practice of medical affairs in medicines development.
- Apply the ethical behavioral framework for multidisciplinary clinical research or therapeutic teams.
- Discuss the role of patients and professional organizations in healthcare.
- Appraise contributions of medical affairs-related functions to successful business conduct within the organization.
- Compare production processes and review product information to ensure compliance with ethical, legal, and regulatory principles.
- Define the rationale for the involvement of the Medical Affairs function in CME/CPD.
- Critically review a clinical research paper.
- Describe principles and processes needed to develop an effective medical strategic/business plan.
- Outline the value of networks and strategic alliances to meet business objectives.
- Describe quality and project management tools and performance improvement concepts to address organizational performance.

MODULE 7: Leadership in Medical Affairs

Program Overview

Leadership has emerged as a critical competency in Medical Affairs. This results from the increasing relevance of the Medical Affairs function in a dynamic healthcare environment with growing external and internal demands. In today's Pharma industry, business success requires strong Medical Affairs Leadership. Existing programs on leadership help provide fundamentals but fall short of addressing the specific challenges and needs of the Medical Affairs professional. With the desire to fill this need and contribute to accelerating the career development of the Medical Affairs professional, the IFAPP Academy, in partnership with the Tufts Center for the Study of Drug Development (Tufts CSDD), developed an online interactive course on the fundamental pillars of leadership applied practically to the realities of the Medical Affairs world.

Dates – Time Commitment – Tuition Costs

TBD	3-5 hours per week	\$3000
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Lectures

1. The Why and What of Authentic and Courageous Leadership
2. Building and Applying Self-Awareness to Leadership
3. Becoming a Strategic Leader and Partner for the Business
4. Leading Teams and Change
 - a. Leading in a Volatile, Uncertain, Complex, Ambiguous (VUCA) World
 - b. Stepping into a leadership role – transition guidance
5. Thought Leadership & Beyond: Being Influential with Peers and Stakeholders to Make the Right Things Happen
6. Being a Sustainable Leader

Key Objectives:

- Understanding your resilience profile (critical for any leader)
- Understanding your leadership style strengths and weaknesses
- Building your leadership development plan

MODULE 8: Digital Technology in Medicines Development

Program Overview

In today's digital age, the healthcare and pharmaceutical industries are rapidly evolving, and so are how medical affairs professionals interact with healthcare stakeholders. To succeed in this dynamic landscape, staying current with the latest trends and developments in digital technologies is crucial. This course is designed to equip medical affairs and other professionals involved in medicines development in the pharmaceutical industry with the necessary knowledge and skills to navigate the digital world and leverage digital tools effectively in their work.

Dates – Time Commitment – Tuition Costs

TBD	3-5 hours per week	\$3000
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Lectures

- Introduction to Digital Medicines Development
- Digital Tools Explained
- Digital Tools in Research and Clinical Development
- Digital Tools in Medical Affairs
- Digital Communications
- The Emerging Regulation of New Technology in Healthcare
- Digital Safety / Risk Management & Ethics
- The Role of Patients in the Design of Digital Tools for Healthcare
- Demonstrating the Value of Digital Approaches (Case Studies)
- Future Technology - What's on the Horizon?

Short Course: HEOR

Program Overview

Participants taking this short course will be able to:

1. Define Health Economics and Outcomes Research (HEOR) and explain its use and methods.
2. Demonstrate how to apply HEOR methodologies and conduct analysis.
3. Explain what HTA is and how it is used to evaluate the value of drugs.
4. Explain how to develop and leverage a Value Evidence Plan.
5. Demonstrate how to generate and communicate value.

Lectures / Webinars

Lecture 1 (Wk 1)	The Principles of HEOR	Laurent Pacheco
Lecture 2 (Wk 2)	Applying the Principles of HE	Laurent Pacheco
Lecture 3 (Wk 2)	Introduction to HTA	Ahmed Shelbaya
Webinar A (Wk 2)	How to Develop and Leverage the Global Value Dossier	Jennifer Stephens
Lecture 4 (Wk 3)	Value Evidence Plan	Jennifer Stephens
Lecture 5 (Wk 3)	Value Generation and Communication	Seema Haider
Webinar B (Wk 3)	How to Generate and Communicate Value	Seema Haider
Capstone Project (Wk 4)	Capstone Project - Final review with faculty and due date	

Dates – Time Commitment – Tuition Costs

Spring Course: 02/26 - 03/24	3-5 hours per week	\$1000
Summer/Fall 2024	3-5 hours per week	\$1000

Short Course: Clinical Trials I

Program Overview

Participants in this short course will become familiar with the following:

1. The importance of Ethics in Research with human subjects.
2. Writing a scientifically sound clinical trial protocol.
3. Identification of the best research sites and the key selection criteria.
4. The importance of adverse events reporting and interpretation.
5. The significant improvement in quality caused by study monitoring.

Lecture 1 (Wk 1)	Ethical Aspects in Clinical Research	Greg Koski
Lecture 2 (Wk 2)	The Clinical Trial Protocol	Kamlesh Thakker
Webinar A (Wk 2)	Ethics and the Publication of Study Results	Chieko Kurihara
Lecture 3 (Wk 2)	The Research Site	Mike Collins
Lecture 4 (Wk3)	Adverse Event Reporting	Stefano Bonato
Webinar B (Wk 3)	Investigator Initiated Protocols	Kamlesh Thakker
Lecture 5 (Wk 3)	Study Monitoring	Roberto Vallalta
Capstone Project (Wk 4)	Capstone Project - Final review with faculty and due date	

Dates – Time Commitment – Tuition Costs

Spring Course: 02/26 - 03/24	3 - 5 hours per week	\$1000
Summer/Fall 2024	3 - 5 hours per week	\$1000

Short Course: Clinical Trials II: the optimal management of clinical trials

Program Overview

Participants in this short course will become familiar with the following:

1. The importance of Project Management to keep control of all details of a trial.
2. How to manage massive amounts of clinical data.
3. The importance of quality in clinical research and how to implement it.
4. The final step of a clinical study: preparing the study report.
5. Some key aspects in clinical trials: failures and new horizons.

Lecture 1 (Wk 1)	Project Management	Mike Collins
Lecture 2 (Wk 2)	Risk-Based and Patient-Centered Monitoring	Mike Collins
Webinar A (Wk 2)	Data Management	Susy Davis
Lecture 3 (Wk 2)	Quality Management	Shoibal Mukherjee
Lecture 4 (Wk3)	The Role of DSMB & CEC in Medicines Development	Kamlesh Thakker
Webinar B (Wk 3)	Study Report	Domenico Criscuolo
Lecture 5 (Wk 3)	Overall Issues in Medicines Development and Virtual Trials	Domenico Criscuolo
Capstone Project (Wk 4)	Capstone Project - Final review with faculty and due date	

Dates – Time Commitment – Tuition Costs

Spring Course: 02/26 - 03/24	3 - 5 hours per week	\$1000
Summer/Fall 2024	3 - 5 hours per week	\$1000

GMDP Academy 2024 Tuition Rates and Scholarships - Certification in Medicines Development (CMD)

Base Program Fee: \$9,800 USD

Corporate Sponsor rates:

Tier and number of students	% of students	Tuition fee per student
Tier I (> 25)	70%	\$8,740
Tier II (15-24)	10%	\$9,000
Tier III (1-14)	5%	\$9,800

Preferential pricing groups:

- **King's College London Invitees:** \$9,000
 - Requires personal invitation code from King's College London.
- **Regulatory/government agencies:** \$4,900
 - Limited to 5% (including the financial support applicants) of final cohort
 - Applicants must provide the following: letter of intent, 2 recommendation letters (one from a supervisor and the second from a colleague)
- **Self-Paid Students scholarships & partial scholarships:**

Flexible payment plans and financial assistance are available. Tuitions range from \$4,900 to \$9,800.

 - To provide educational opportunities to self-paid students in a wide variety of countries with varying economic statuses, the Academy offers a *limited number of partial scholarships based on several factors (including, but not limited to: country of residence, economic need, employment status, employer).

*The Academy reserves the right to limit the number of partial scholarships to 5 students or 5% of the final number of new attending students (including the regulatory/government agency applicants).

 - 2 Full scholarships may be awarded for particularly well-qualified individuals

Eligibility requirements:

- Applicants must not be employed by a pharmaceutical company
- Applicant must meet minimum student entry requirements for the program (see above section)
- Applicants must provide the following: a personal letter of intent and two recommendation letters (one from a supervisor and the second from a colleague)