INSTITUTE
OF MEDICINE

ROYAL COLLEGE OF
PHYSICIANS OF IRELAND

HIGHER SPECIALIST TRAINING IN

PHARMACEUTICAL MEDICINE

OUTCOME-**B**ASED **E**DUCATION – OBE CURRICULUM

This curriculum of Higher Specialist Training in Pharmaceutical Medicine was developed in 2023 by a working group led by Dr Anthony Chan, National Specialty Director, and the RCPI Education Department. The Curriculum undergoes an annual review process by National Specialty Director, and the RCPI Education Department. The Curriculum is approved by the Specialty Training Committee and the Institute of Medicine.

Version	Date Published	Last Edited By	Version Comments
1.0	01 July 2024	Stephen Capper	New OBE Curriculum

National Specialty Director's Foreword

The Pharmaceutical Medicine HST Programme, along with the BST training from an approved list of recommended specialties, aims to deliver expert pharmaceutical Physicians with a broad range of skills needed for the continually developing specialty.

Development of the Outcome Based Education (OBE) curriculum started in early 2023. It was decided that a hybrid model of curriculum review would be the best use of time for the STC's subject matter experts. A series of initial live online review and drafting of the core and specialty modules for each of the 6 core sections took place with STC SME's. A workshop then took place at RCPI to collate the review deliverables, involving the whole STC membership, where multiple perspectives were discussed, captured and consensus reached. The final version was reviewed by all STC membership. I would like to thank all the STC members who devoted their time to this process.

The Outcome Based Education (OBE) curriculum makes the transition from the previous minimum requirements model of training, to become better aligned with international best practices and standards around the globe. This involves a substantial change to the structure of the curriculum, but most of the curriculum assessments and objectives remain the same – to produce well-rounded specialists with the ability to practise independently, while supporting the development of subspecialty expertise and interests. Training goals are aligned to key areas of practice. Trainees will demonstrate proficiencies in each outcome matched to the level of their training, progressing to independent competence in each.

Fulfilment of the HST requirements will result in the award of a Certificate of Satisfactory Completion of Specialist Training (CSCST) in Pharmaceutical Medicine. Trainees completing this HST programme will acquire a breadth of experience and be fully prepared for independent practice.

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1. INTRODUCTION

This section includes an overview of the Higher Specialist Training programme and of this Curriculum document.

1.1. Purpose of Training

This programme is designed to provide training in Pharmaceutical Medicine in approved training posts, under supervision, to fulfil agreed curricular requirements. Each post provides a trainee with a named trainer and the programme is under the direction of the National Specialty Director for Pharmaceutical Medicine.

1.2. Purpose of the Curriculum

The purpose of the Curriculum is to guide the Trainee towards achieving the educational outcomes necessary to work as an independent Pharmaceutical Medicine Physician. The Curriculum defines the relevant processes, content, outcomes, and requirements to be achieved. It stipulates the overarching goals, outcomes, expected learning experiences, instructional resources and assessments that comprise the Higher Specialist Training (HST) programme. It provides a framework for certifying successful completion of HST programme.

In keeping with developments in medical education and to ensure alignment with international best practice and standards, the Royal College of Physicians (RCPI) have implemented an Outcomes Based Education (OBE) approach. This curriculum design differs from traditional minimum requirement designs in that the learning process and desired end-product of training (outcomes) are at the forefront of the design to provide the essential training opportunities and experiences to achieve those outcomes.

1.3. How to use the Curriculum

Trainees and Trainers should use the Curriculum as a basis for goal-setting meetings, delivering feedback, and completing assessments, including appraisal processes (Quarterly Assessments/End of Post Assessment, End of Year Evaluation). Therefore, it is expected that both Trainees and Trainers familiarise themselves with the Curriculum and have a good working knowledge of it.

Trainees are expected to use the Curriculum as a blueprint for their training and record specific feedback, assessments, and training events on ePortfolio. The ePortfolio should be updated frequently during each training placement.

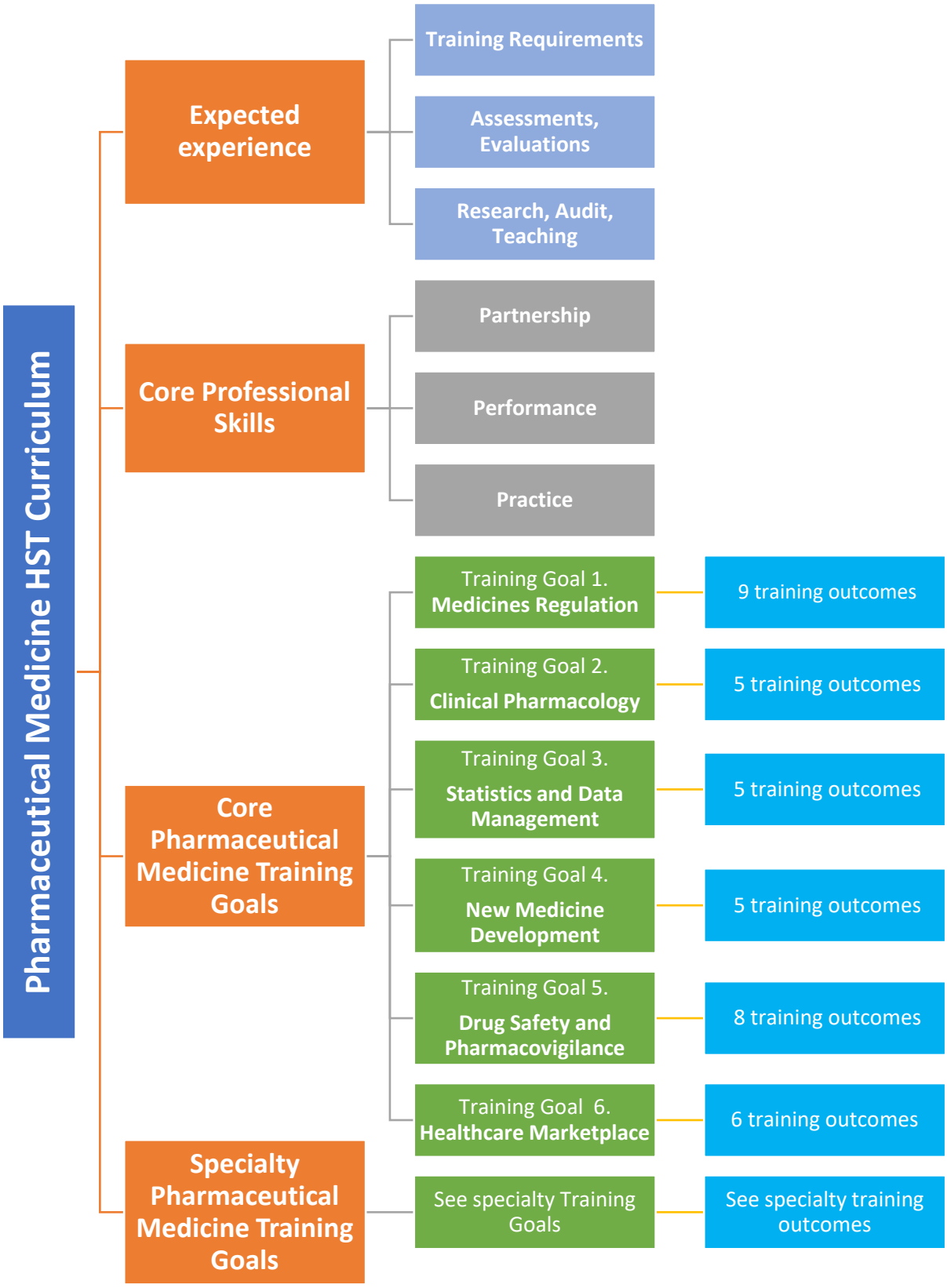
It is important to note that ePortfolio is a digital repository designed to reflect Curriculum requirements. It facilitates recording of progress through HST and evidence that training is valid and appropriate. While a complete ePortfolio is essential for HST certification, Trainees and Trainers should always refer to the Curriculum in the first instance for information on the requirements of the training programme.

Please note: It is the responsibility of the Trainee to keep an up-to-date ePortfolio throughout the programme as it reflects their individual training experience and it documents that they have successfully met training standards as expected by the Medical Council.

1.4. Reference to rules and regulations

Please refer to the following sections within the Pharmaceutical Medicine HST Training Handbook for rules and regulations associated with this post. Policies, procedures, relevant documents, and Training Handbooks can be accessed on the RCPI website following this link.

1.5 Overview of Curriculum Sections and Training Goals



2. EXPECTED EXPERIENCE

This section details the training experience that all Trainees are expected to complete over the course of the Higher Specialist Training.

2.1. Duration and Organisation of Training

Whilst the curriculum is outcomes based, the duration of training must meet the European minimum of 4 years for full-time speciality training adjusted accordingly for flexible training. The curriculum incorporates the European harmonised curriculum for pharmaceutical medicine, formally approved by the European Commission recognised Innovative Medicines Initiative Joint Undertaking (IMIJU) PharmaTrain project.

Core Training: The programme considers the major areas of competence required by the pharmaceutical medicine (PM) specialist. There are six sets of core training goals and five sets of specialty training goals, in addition to the core professional skills. Trainees must demonstrate proficiency in each of the core training goals, including at least one set of specialty module training goals during their period of training.

In addition, each trainee must complete a postgraduate course (diploma/MSc) in pharmaceutical medicine / drug development sciences, by the end of year 3 of the training programme. This is funded by the trainee's employer or self-funded. This will enable trainees to demonstrate that they have a broad understanding of the most important areas of pharmaceutical medicine and its overarching public health role in the promotion of the rational use of medicines.

Trainees in the Pharmaceutical Medicine HST programme are encouraged to spend time in clinical research. However, due to the nature of the specialty there is no period of research or out of programme experience that will count towards the completion of the training program. Many of the core Training Goals already incorporate significant research elements. If trainees express an interest in undertaking clinical research during the training programme they may do so as part of the New Medicines Development specialty module. The Pharmaceutical Medicine NSD and Dean of Postgraduate Medical Education & Training will review the application prospectively for appropriateness of the research topic and the candidate to undertake the work. For those intending to pursue an academic path, an extended period of research may be necessary to explore a topic fully or to take up an opportunity of developing the basis of a future career. Such extended research may continue after the CSCST is gained.

The earlier years of training will usually be directed towards acquiring a broad general experience of Pharmaceutical Medicine under appropriate supervision. An increase in the depth of content from hands-on experience follows naturally, and, as confidence is gained and capabilities are acquired, the trainee will be encouraged to assume a greater degree of responsibility and independence.

Core Professional Skills: Core professional knowledge, skills and attitudes support competencies which are common to good medical practice in all the Medical and related specialties. It is intended that all trainees should reaffirm relevant competencies during Higher Specialist Training. No timescale of acquisition is offered, but failure to make progress towards meeting these important objectives at an early stage would cause concern about a Trainee's suitability and ability to be capable as an independent specialist.

Training Programme: Due to the nature of the specialty and in particular the confidential nature of much of the work undertaken by professionals working in the various strands of pharmaceutical medicine, it will not usually be possible for trainees to routinely rotate between training sites. Where the potential training site is within a large organisation (e.g., large pharmaceutical companies, national regulatory agencies such as the HPRA), it may be possible for the trainee to gain workplace experience in most of the areas listed as core pharmaceutical medicine competences within the training programme at their training site. Moreover, many of the smaller potential training sites are affiliates of larger EU-based institutions, therefore the trainee may be able to access experience from within the larger organisation; however, the trainee may still be required to participate in external practical workshops to acquire competence as per curricular requirements.

All potential training sites will be approved prior to start of training. This will involve a site visit by the RCPI to the training site and require a signed commitment by the employer to ensure that the trainee's role and responsibilities will be compatible with his/her training role in Pharmaceutical Medicine. This includes adequate time for study and periods of study leave. The elements of the programme which can be delivered by "On Site Experience" will be identified; those that will require external training will also be identified and trainee and Trainer will work towards a solution that will be agreed with the NSD and endorsed by the Specialty Training Committee. Trainees will also be required to complete all the mandatory RCPI HST courses as listed in the requirements section of the curriculum.

Any deficiencies arising from the lack of rotation will be overcome by (1) requiring each trainee to successfully complete a recognised postgraduate course in pharmaceutical medicine/drug development sciences and (2) the use of problem-based learning workshops/practical sessions. Trainees, whose employment site precludes/offers limited workplace experience in a specific competence, will be required to complete a workshop / practical session in that area of competence. These may be run by the various training sites where such competences are available, or in approved academic institutions, as approved from time to time by the Specialty Training Committee. All trainees may attend these sessions, which will help to develop an in-depth understanding of the area through problem-based learning activities and will also promote interactive learning relationships between the trainees on the programme.

2.2. Training and Educational activities

Pharmaceutical Medicine trainees are expected to engage in a range of training and educational activities over the course of their training programme. These experiences range from gaining management experience, engaging in the delivery of teaching sessions, conducting audit and quality improvement, research activities, attending national and international meetings.

The timetable and frequency of attendance should be agreed with the assigned trainer at the beginning of the post. All these activities should be recorded on ePortfolio using the respective form.

Recording of Evidence of training: The target numbers for training items in the following sections represent the recording requirement to document evidence of relevant and varied experiences; it is understood that actual number of training experiences is likely to be well in excess of these numbers.

2.3. In-house commitments

Trainees are expected to attend a series of in-house commitments as follows:

- Attend at least **1 educational literature review session per month**
- Attend at least **1 departmental management meeting per month**

2.4. Teaching, Audit and Research experiences

Trainees are expected to complete the following activities:

- Deliver **4 Teaching/Tutorial Sessions** per year of training
- Complete **1 Audit** per year of training (as per Medical Council of Ireland PCS requirement)
- Complete **2 Quality Improvement Projects** over the training programme
- Attend **2 National or International academic meetings relevant to his/her role** over the training programme

In addition, it is desirable that Trainees aim to

- Deliver **1 Oral presentation or Poster at a national or international academic meeting** per year of training
- Complete **1 research project and/or 1 publication** over the training programme

2.5. Teaching attendance

Trainees are expected to attend all the mandatory courses and study days as detailed in the Teaching Appendix, at the end of this document.

2.6. Evaluations, Examinations and Assessments

Trainees should, as a minimum, complete:

- **4 quarterly evaluations per training year** (1 evaluation per quarter)
- **1 end of post evaluation at the end of each post** (this can replace the quarterly evaluation)
- **1 end of year evaluation at the end of each training year**
- **4 Pharmaceutical Medicine Assessments (PMAT) or Project-based Discussions (PbD) for each training year**
- approved **Postgraduate Pharmaceutical Medicine course, at diploma or MSc level (by end of year 3)**

For more information on evaluations, and assessment, please refer to the Assessment Appendix at the end of this document.

2.7. Summary of Expected Experience

Experience Type	Trainee is expected to	ePortfolio form
Core/Specialty modules Requirements	Complete all requirements related to the core and specialty modules agreed	n/a
Personal Goals	At the start of each year, complete a Personal Goals form on ePortfolio, as agreed with Trainer	Personal Goals
Additional Professional Experience	Gain additional professional experience as indicated above and agreed with Trainer. Record on ePortfolio	Additional Professional Experience
Management Experience	Gain management experience as agreed with Trainer	Management Experience
Deliver Teaching	Record all delivered Teaching/Tutorial sessions	Delivery of Teaching
Research	Desirable Experience: actively participate in research, seek to present at least 1 piece of research at conferences or national/international meetings during the training programme	Research Activities
Publication	Desirable Experience: complete 1 publication during the training programme	Additional Professional Experience
Presentation	Desirable Experience: Deliver 1 oral presentations on relevant subject per year of training	Additional Professional Experience
Audit and quality improvement	Complete and report on an audit per year of training. Complete 2 Quality Improvement Projects over the training programme	Audit and QI
National/International Meetings	Attend 2 over the training programme. Record attendance on ePortfolio	Additional Professional Experience
Teaching Attendance	Attend courses and Study Days as detailed in the Teaching Appendix. Record attendance on ePortfolio	Teaching Attendance
Pharmaceutical Medicine Assessments	Complete all required assessments in agreement with assigned trainer	Reports/Pharmaceutical Medicine Assessments
Examinations	Complete postgraduate course (diploma/MSc) in Pharmaceutical Medicine/Drug Development Sciences with associated assessments	Examinations
Quarterly and/or End-of-Post Evaluations	Complete a Quarterly Assessment/End of post assessment with Trainer 4 times in each year. Discuss progress and complete the form	Quarterly Assessments/End-of-Post Assessments
End of Year Evaluation	Prepare for the End of Year Evaluation. Ensure the portfolio is up to date. End of Year Evaluation form is completed in co-ordination with the assigned Trainer	End of Year Evaluation

3. CORE PROFESSIONAL SKILLS

This section includes the Medical Council guidelines for medical professional conduct, regarding Partnership, Performance and Practice.

These principles are woven within training practice and feedback is formally provided in the Quarterly Evaluations, End of Post, End Year Evaluation.

Partnership

Communication and interpersonal skills

- Facilitate the exchange of information, be considerate of the interpersonal and group dynamics, and have a respectful and honest approach
- Engage with public and colleagues in a respectful manner
- Actively listen to the thoughts, concerns, and opinions of others
- Consider data protection, and appropriate modes of communication when exchanging information with others

Collaboration

- Collaborate, and colleagues to work in the best interest of the patient, for improved services and to create a positive working environment
- Work cooperatively with colleagues and team members to deliver an excellent standard of practice
- Seek to build trust and mutual respect with public
- Appropriately share knowledge and information, in compliance with GDPR guidelines
- Take on-board available, relevant feedback

Health Promotion

- Communicate and facilitate discussion around the effect of lifestyle factors on health and promote the ethical practice of evidence-based medicine
- Seek up-to-date evidence on lifestyle factors that:
    - negatively impact health outcomes
    - increase risk of illness
    - positively impact health and decrease risk factors
- Actively promote good health practices with patients individually and collectively

Ethics

- Be familiar with ethical frameworks relevant to Pharmaceutical Physicians including
    - The International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP) ethical framework. Link
    - The World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. Link
    - The Shared Ethical Responsibility of Medically and Non-medically Qualified Experts in Human Drug Development Teams. Link
    - Local and national clinical care guidelines
- Act in the patient's/publics best interest
- Engage in shared decision-making and discuss consent where appropriate

Performance

Safety and ethical practice

- Follow safe working practices
- Understand ethical practice and the medical council guidelines
- Support a culture of open disclosure and risk reporting
- Be aware of the risk of abuse, social, physical, financial, and otherwise, to vulnerable persons

Organisational behaviour and leadership

- Understand the activities, personnel and resources that impact the functioning of the team
- Understand and work within management systems
- Know the impacts of resources and necessary management
- Demonstrate proficient self-management

Wellbeing

- Be responsible for own well-being and health and its potential impact on the team, department and company deliverables
- Be aware of signs of poor health and well-being
- Be cognisant of the risk related to poor health and well-being of self and colleagues
- Manage and sustain own's physical and mental well-being

Practice

Continuing competence and lifelong learning

- Continually seek to learn, improve clinical skills and understand established and emerging theories in the practice of medicine
- Meet career requirements including those of the medical council, employer, and training body
- Be able to identify and optimise teaching opportunities in the workplace and other professional environments
- Develop and deliver teaching using appropriate methods for the environment and target audience

Reflective practice and self-awareness

- Bring awareness to actions and decisions and engage in critical appraisal of own's work to drive lifelong learning and improve practice
- Pay critical attention to the practical values and theories which inform everyday practice
- Be aware of own's level of practice and learning needs
- Evaluate and appraise decisions and actions with consideration as to what you would change in the future
- Seek to role model good professional practice within your place of work

Quality assurance and improvement

- Seek opportunities to promote excellence and improvements in clinical care through the audit of practice, active engagement in and the application of clinical research and the dissemination of knowledge at all levels and across teams
- Gain knowledge of quality improvement methodology
- Follow best practices in patient safety
- Conduct ethical and reproducible research

4. SPECIALTY SECTION – CORE PHARMACEUTICAL MEDICINE TRAINING GOALS

*This section includes the Core Pharmaceutical Medicine Training Goals. The Trainee is expected to achieve proficiency in **ALL** Core Training Goals by the end of Higher Specialist Training.*

Each Training Goal is broken down into specific and measurable Training Outcomes.

*Under each Outcome there is an indication of the suitable and **recommended** training/learning opportunities and assessment methods.*

In order to achieve the Outcomes, it is recommended to agree the most appropriate training and assessment methods with the assigned Trainer.

Core Training Goal 1 – Medicines Regulation

By the end of Pharmaceutical Medicine Training, the Trainee is expected to acquire and demonstrate a working knowledge of medicines regulation both at National, EU and International level, and to be able to apply this knowledge throughout the course of the medicinal product life cycle; to understand, and demonstrate ability to, perform one's duties within the legislative framework.

Outcome 1 – Knowledge of national, EU, and international regulations and guidelines

For the Trainee to demonstrate and apply knowledge of current National, EU and International regulations, Good Clinical Practice (GCP) guidelines and ethics committee requirements and regulatory review procedures in the assessment, development, and the undertaking of clinical trials.

Outcome 2 – Explain EU regulatory approval procedures, to write or appraise clinical expert reports

For the Trainee to explain EU regulatory approval procedures and contribute to the writing and/or appraisal of a clinical expert report.

Outcome 3 – Knowledge of structure and function of EU commission and EMA

For the Trainee to demonstrate knowledge of the structure and function of the EU commission and European Medicines Agency (EMA) with respect to medicines regulation, and describe the differences between Regulations, Directives and Guidelines.

Outcome 4 – Awareness of EU CHMP guidelines and impact on medicinal product life cycle

For the Trainee to demonstrate an awareness of the EU CHMP guidelines, and the impact on the medicinal product life cycle.

Outcome 5 – Knowledge of role ICH guidelines including common technical document

For the Trainee to demonstrate knowledge of the role of ICH guidelines including the Common Technical Document.

Outcome 6 – Outline regulatory requirements for product information

For the Trainee to outline the regulatory requirements for product information: SmPC, PIL, Package labelling, technical leaflets.

Outcome 7 – Knowledge of post authorisation procedures

For the Trainee to demonstrate a working knowledge of post authorisation procedures, including risk-management plan and other specific obligations, and maintenance of marketing authorisations (including removal of a medicine from the marketplace).

Outcome 8 – Awareness of legal requirements for legal classification or change in classification of medicinal products

For the Trainee to demonstrate awareness of legal requirements for legal classification and change in classification of medicinal products.

Outcome 9 – Describe HPRA guidance for supply of exempt/unauthorised medicinal products

For the Trainee to describe the HPRA guidance for supply of exempt/unauthorised medicinal products.

Assessment & Learning Methods

Courses

• Ethics Foundation

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

• Develop a summary document describing the European centralised, decentralised & mutual recognition procedures for Marketing Authorisation, and the role of the CTD
• Create a risk management plan for a medicinal product (real or hypothetical).

• Complete an amendment (variation) application to a marketing authorisation for Types IA, IB, II

• Complete **at least one** reflective commentary of the module

Core Training Goal 2 – Clinical Pharmacology

By the end of Pharmaceutical Medicine Training, the Trainee is expected to achieve proficiency in exercising judgement on the clinical pharmacology of a medicinal product in all phases of its research and development to facilitate the stepwise process towards marketing authorisation approval and beyond. To be able to obtain and apply therapeutic area knowledge in the identification of unmet therapeutic needs. To demonstrate proficiency in all aspects of the conduct of early phase clinical trials (Phase 1 and Phase 2), including regulatory and ethical aspects.

Outcome 1 – Identify non-clinical evidence to determine suitability of an investigational product for clinical development

For the Trainee to identify the non-clinical evidence required to determine an investigational product's suitability to proceed to clinical development.

Outcome 2 – Review and interpret pre-clinical animal toxicology of investigational product

For the Trainee to review and interpret the pre-clinical animal toxicology data of an investigational product before first in human trial is initiated, as part of a multidisciplinary team.

Outcome 3 – Evaluate data from early clinical pharmacology studies

For the Trainee to evaluate the data from the early clinical pharmacology studies (phase 1) of an investigational product data before phase 2 clinical trials are initiated.

Outcome 4 – Review design of clinical pharmacology studies/programme

For the Trainee to define and review the design of additional clinical pharmacology studies to support the clinical development programme.

Outcome 5 – Implement regulatory requirements

For the Trainee to implement the regulatory requirements, GCP, and ethical provision in the design, conduct and analysis of clinical pharmacology studies, including informed consent documentation.

Assessment & Learning Opportunities

Courses

- Ethics Foundation
- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

- Prepare a written report on the impact of differences of in vivo drug handling in two patient subgroups on drug development (e.g., children versus the elderly; normal versus reduced renal or hepatic function).
- Critically appraise an early phase clinical trial.
- Report on clinical pharmacology aspects unique to a specific therapeutic area.

- Complete **at least one** reflective commentary of the module.

Core Training Goal 3 – Statistics and Data Management

By the end of Pharmaceutical Medicine Training, the Trainee is expected to achieve proficiency in the understanding of common statistical concepts, and their usage in clinical research to analyse clinical data. To demonstrate awareness of the critical clinical elements of study design, data management, analysis, and reporting of clinical trial data to meet scientific and regulatory standards. To be able to evaluate alternative sources of data, including meta-analysis and real-world evidence.

Outcome 1 – Review a statistical analysis plan

For a Trainee to critique a Statistical Analysis Plan, including sample size calculations, the selection of primary and secondary endpoints, choice of comparator and methods of analyses.

Outcome 2 – Critical appraisal of a pivotal study

For the Trainee to conduct a critical appraisal of a publication of a pivotal study, focusing on the statistical methodology and results.

Outcome 3 – Understanding of statistical principles/methods in clinical development

For the Trainee to demonstrate understanding of commonly used and emerging statistical principles & methods in clinical development, post marketing and health economic studies, and recognise the importance of the use of appropriate statistical methodology to allow for the correct interpretation.

Outcome 4 – Understanding of principles/challenges of Case Report

For the Trainee to demonstrate an understanding of the key principles and challenges of Case Report Form design, data quality management to minimise errors in data collection, and to understand the data cleaning and reconciliation process.

Outcome 5 – Importance of compliance, consent, and data privacy

For the Trainee to appreciate the importance of compliance to prevailing regulations on consent and data privacy in managing trial subject datasets.

Assessment & Learning Opportunities

Courses

- Introduction to Health Research (Year 1)
- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3
- **Desirable:** completion of an academically recognised biostatistics course

Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

- Perform a critique of the statistical aspects of an agreed specific clinical study protocol
- Complete a data review of a clinical study report, including assessments of protocol deviations, violations & withdrawals.
- Complete **at least one** reflective commentary of the module

Core Training Goal 4 – New Medicine Development

By the end of Pharmaceutical Medicine Training, the Trainee is expected to develop a thorough working knowledge of all aspects of drug development. To acquire the competency to prepare a constructive overview of the disease area and demonstrate the relevance of developing a medicinal product in this area. To critique a clinical development plan of a new medicinal product that would be approvable by National and/or International regulatory agencies.

Outcome 1 – Critically review components of clinical development plan

For the Trainee to demonstrate an ability to critically review the components of Clinical Development Planning, including but not limited to:

TARGET DISCOVERY AND SCREENING

- Disease target identification and selection
- Patenting new active substances-therapeutics, epitope specificity etc.

PRECLINICAL DEVELOPMENT

EARLY-STAGE CLINICAL DEVELOPMENT

FULL CLINICAL DEVELOPMENT & OPERATIONS

- Phase I/II interface: Proof of Concept; Go/No-Go decision points
- Phase II/III interface: Regulatory agency engagement
- Integration into the regulatory submission dossier (i.e., module 2) for licensing of new medicines

Outcome 2 – Assess design and conduct of studies for a medicinal product

For the Trainee to assess the design and conduct of studies for a medicinal product (real or hypothetical).

Outcome 3 – Ethical Principles in undertaking clinical research

For the Trainee to demonstrate understanding of the ethical principles in undertaking clinical research by drafting/reviewing informed consent form in compliance with ICH-required elements, in appropriate, patient-friendly language (write or review).

Outcome 4 – Summarise results of programme of clinical research

For the Trainee to critically summarise the results of a programme of clinical research.

Outcome 5 – Review proposed label based on clinical programme

For the Trainee to be able to review the proposed label based on the clinical programme.

Assessment & Learning Methods

Courses

• Ethics Foundation

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

• **Desirable:** Complete a recognised interactive training programme on protocol development

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

• Critically review a clinical development plan for a new medicinal product (using published or internal data)

• Ability to list required sections of an informed consent form and to have written a complete pre-consent patient information document

• Demonstrate understanding of EU clinical trial regulation and GCP

• Critically appraise a European Public Assessment Report (for a new active substance)

• Write **at least one** reflective commentary of the module

Core Training Goal 5 – Drug Safety and Pharmacovigilance

By the end of Pharmaceutical Medicine Training, the Trainee is expected to acquire and demonstrate knowledge of and competency in the safety surveillance of medicinal products during their life cycle. Based on the principles of international regulatory reporting requirements, to understand the monitoring of safety data using appropriate surveillance methods, thereby ensuring protection of patients and clinical trial subjects.

Outcome 1 – Describe good pharmacovigilance practices

For the Trainee to describe good pharmacovigilance practice (GPvP) including ICH / CHMP guidelines and the CIOMS Working Groups Reports on safety surveillance.

Outcome 2 – Explain how adverse event are reported and assessed

For the Trainee to explain how suspected adverse events are reported and assessed both in terms of clinical studies and post-marketing.

Outcome 3 – Identify the requirement for safety regulatory actions

For the Trainee to be able to identify the requirement for safety regulatory actions as appropriate including Marketing Authorisation (MA) variations, urgent safety restrictions, MA suspension and withdrawal.

Outcome 4 – Evaluate individual case reports

For the Trainee to evaluate individual case reports for completeness so as to determine causality assessment.

Outcome 5 – Evaluate product quality defects complaints

For the Trainee to evaluate the product quality defects complaints (PQCs) to identify a possible adverse event.

Outcome 6 – Evaluation of aggregate safety data

For the Trainee to understand evaluation of aggregate safety data, e.g., Periodic Safety Update report (PSUR).

Outcome 7 – Principles and methods for risk/benefit evaluation

For the Trainee to describe the principles and methods for risk/benefit evaluation and related decisions during the product life cycle.

Outcome 8 – Describe make-up and operations of crisis management team

For the Trainee to describe the make-up and operations of a crisis management team to manage urgent safety issues, including market actions and generation of appropriate communications to regulatory bodies, healthcare professionals, patients, and general public.

Assessment & Learning Methods

Courses

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

• Describe the requirements and processes for reporting of safety information to the HPRA (in Ireland) and to the EMA, and implementation of appropriate follow up measures.
• Assess the serious adverse events (SAEs) from a clinical trial and determine their causal relationship to the study drug and their expectedness
• Evaluate a PSUR

• Review spontaneous case reports evaluating seriousness, relatedness and reportability

• Perform a critique of the safety section of an SmPC and a PIL

• Write **at least one** reflective commentary of the module

Core Training Goal 6 – Healthcare Marketplace

By the end of Pharmaceutical Medicine Training, the Trainee is expected to demonstrate proficiency in keeping the welfare of patients at the forefront in the promotion of approved medicinal products. To describe how a Pharmaceutical Physician ensures that marketing and educational activities in the healthcare environment are and remain appropriate, ethical, and legal.

Outcome 1 – Key elements in development of compliant marketing/medical communications

For the Trainee to describe the key elements in development of compliant marketing and/or medical communications, including but not limited to the approval process involved in the preparation and production of compliant documentation to support medical and/or marketing activities (SI 541 and IPHA Code of Practice).

Outcome 2 – Evaluation of medical landscape in relation to emerging pharmaceutical products

For the Trainee to describe the information required to undertake an evaluation of the medical landscape relevant to current or emerging pharmaceutical products in Ireland so as to generate the medical brand plan.

Outcome 3 – Interact appropriately with external stakeholders

For the Trainee to interact appropriately with the external healthcare stakeholders, such as healthcare professionals, patient advocacy groups, payers and the public (this includes a role in medical information function).

Outcome 4 – Ethical challenges in both commercial and professional aspects

For the Trainee to describe the ethical challenges that arise in balancing the commercial and medical professional aspects within the legal/regulatory framework.

Outcome 5 – Application of principles of economics of healthcare

For the Trainee to be able to demonstrate understanding and be able to apply the principles underlying the Economics of Healthcare and the basic principles underlying pharmacoeconomic evaluation and evidence-based medicine including but not limited to,

• Principles of healthcare economics; principles of justice and equity in healthcare economics, principles of pharmacoeconomic, and outcomes research.

• Health Technology Assessment including meta-analysis and systematic review; health economics evaluation studies.

Outcome 6 – Able to train staff and deliver presentations

For the Trainee to be able to train staff within an organisation and deliver presentation to external stakeholders.

Assessment & Learning Opportunities

Courses

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT) Assessments

Assessments

• Design a medical brand plan for a medicinal product

• Critically analyse an HTA

• Perform a competitive product analysis

• Perform a critical analysis of a complaint regarding promotional material or activities

• Deliver internal training

• Deliver external presentations

• Write **at least one** reflective commentary on the module

5. SPECIALTY SECTION – SPECIALTY PHARMACEUTICAL MEDICINE TRAINING GOALS

*This section includes the Specialty Pharmaceutical Medicine Training Goals. The Trainee is expected to achieve proficiency in at least **ONE** of the Specialty Training Goals by the end of Higher Specialist Training.*

Each Training Goal is broken down into specific and measurable Training Outcomes.

*Under each Outcome there is an indication of the suitable and **recommended** training/learning opportunities and assessment methods.*

In order to achieve the Outcomes, it is recommended to agree the most appropriate training and assessment methods with the assigned Trainer.

Specialty Training Goal 1 – Medicines Regulation II

By the end of Pharmaceutical Medicine Training, the Trainee is expected to demonstrate a working knowledge of medicines regulations, both in EU and outside the EU, and to be able to apply this knowledge in drug development, counterfeit products, and other miscellaneous pharmaceutical procedures & requirements. To have a working knowledge of Pharmacovigilance requirements in the EU and in the other ICH regions specifically relating to risk management.

Outcome 1 – Understanding of regulations in EU, US, and other jurisdictions

For the Trainee to demonstrate an in-depth understanding of prevailing regulations in the EU, US and other major regulatory jurisdictions and appraise key differences between the various regulatory frameworks, demonstrating knowledge and awareness of the role of relevant ICH Guidelines.

Outcome 2 – Knowledge of procedures around counterfeit medicines

For the Trainee to have a working knowledge and awareness of the procedures around counterfeit medicines.

Outcome 3 – Awareness of requirements for regulation of medicines/products/devices

For the Trainee to demonstrate an awareness of the requirements for regulation of herbal/botanical, orphan medicines, paediatric medicines, advanced therapy medicinal products, and medical devices regulations as applicable to medicinal products.

Outcome 4 – Appraise use of real-world evidence

For the Trainee to demonstrate ability to appraise use of real-world evidence in medicines registration.

Assessment & Learning Methods

Courses

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT) – Including peer reviewed documents/reports

Assessments

• Describe key differences of an application for a generic drug in the EU vs another jurisdiction

• Complete a workshop on regulatory submission and regulation

• Critique an application for an orphan drug designation

• Critique a Paediatric Investigational Plan (PIP)

• Write **at least one** reflective commentary on the module

Specialty Training Goal 2 – Clinical Pharmacology II

By the end of Pharmaceutical Medicine Training, the Trainee is expected to demonstrate proficiency in the implementation of all aspects of early-phase clinical trials, including their regulatory and ethical aspects.

Outcome 1 – Plan and undertake clinical pharmacology study

For the Trainee to demonstrate an ability to plan and undertake a clinical pharmacology study of a new medicinal product.

Outcome 2 – Review/author study reports and/or clinical overviews

For the Trainee to review/author Study Reports and/or Clinical Overviews in accordance with regulatory requirements.

Assessment & Learning Opportunities

Courses

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

- Develop an investigational plan for a potential new medicinal product by applying key pharmacology principles
- Critique a clinical study report from a clinical pharmacology study
- Design a Drug-drug interaction (DDI) study
- Complete **at least one** reflective commentary of the module

Specialty Training Goal 3 – New Medicine Development II

By the end of Pharmaceutical Medicine Training, the Trainee is expected to undertake research and appraise constructively and report on the evidence of safety and efficacy of a new medicinal product and assess its benefits, risks, and place in the practice of clinical medicine. To apply statistical analysis methodologies and techniques for collected data, and appropriately present the data as part of the clinical section of regulatory submission.

Outcome 1 – Contribute to development of clinical study

For the Trainee to meaningfully contribute to the development and conduct of a clinical study - from study protocol, setup, conduct, data collection, data reconciliation, to database closure.

Outcome 2 – Contribute to development of a Statistical plan

For the Trainee to contribute to the development of a SAP, including finalisation of the shells for the tables figures and listing.

Outcome 3 – Interpret results of a statistical analysis

For the Trainee to interpret the results of a statistical analysis of data based on standardised methods, including survival analysis & meta-analysis, as well as identifying secondary research parameters out of primary dataset/s.

Outcome 4 – Describe how clinical data fits with clinical development programme

For the Trainee to describe how the clinical data from this study fit into the overall clinical development programme, and the role it plays in the overall regulatory submission.

Assessment & Learning Methods

Courses

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

• Perform a medical review of a clinical study report for which you played a meaningful role

• Critique a briefing book for a major regulatory interaction pertaining submission of a medicinal product

• Complete **at least one** reflective commentary of the module

Specialty Training Goal 4 – Drug Safety and Pharmacovigilance II

By the end of Pharmaceutical Medicine Training, the Trainee is expected to acquire a deeper level of knowledge and demonstrate proficiency in drug safety and pharmacovigilance including international aspects, and the implementation of required actions when safety issues arise.

Outcome 1 – Construct safety sections of SmPC

For the trainee to be able to construct the safety sections of the Summary of Product Characteristics (SmPC) and PIL according to regulatory requirements.

Outcome 2 – Demonstrate awareness of signal detection methodologies

For the trainee to demonstrate awareness of signal detection methodologies in the evaluation of potential safety signals of marketed medicinal products from all sources (including spontaneous reports, solicited data, literature) to monitor the ongoing benefit/risk for the medicinal product.

Outcome 3 – Contribute to development of drug safety reports

For the trainee to contribute to the development of drug safety reports for marketed medicines e.g., PSUR (periodic safety update report).

Outcome 4 – Contribute to development of RMP/PASS

For the trainee to contribute to the development of the risk management plan (RMP), and, if appropriate, the post-authorisation safety study (PASS).

Outcome 5 – Establish and direct crisis management committee

For the trainee to be able to establish and direct a crisis management committee to manage urgent safety issues, up to and including product recall and the management of appropriate communications to regulatory bodies, healthcare professionals, patients, and the general public.

Assessment & Learning Methods

Courses

• Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

• Project-based Discussion (PbD)

• Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

• Author a fictional or real “Dear Healthcare professional” letter

• Write the overall safety evaluation section of a PSUR (real or simulated)

• Lead a simulated crisis management scenario

• Critical analyse one RMP

• Write **at least one** reflective commentary on the module

Specialty Training Goal 5 – Healthcare Marketplace II

By the end of Pharmaceutical Medicine Training, the Trainee is expected to be familiar with all the elements associated with reimbursement including the elements required in Health Technology assessment, to understand the requirements of a quality management system in a company and to fully understand the complex relationship with other stakeholders.

Outcome 1 – Evaluation of requirements for product reimbursement

For the Trainee to be able to perform an evaluation of the requirements for product reimbursement including clinical evidence, outcomes research, health economic evaluation and HTA.

Outcome 2 – Review and approve market research questionnaire and Advisory Board materials

For the Trainee to be able to review and approve a market research questionnaire and advisory board materials (including its format).

Outcome 3 – Understanding of components and operation of quality management system

For the Trainee to demonstrate comprehensive understanding of the requirements for the components and operation of a company quality management system.

Assessment & Learning Methods

Courses

- Completion of a recognised Postgraduate course in Pharmaceutical Medicine by end of year 3

Assessment Tools

- Project-based Discussion (PbD)
- Pharmaceutical Medicine Assessment Tool (PMAT)

Assessments

- Author the medical section of a health economic evaluation
- Create a local SOP covering a GXP function
- Review and approve a market research questionnaire
- Plan and conduct a medical advisory board
- Write at least **one** reflective commentary on the module

6. APPENDICES

This section includes two appendices to the Curriculum.

The first one is about Assessment (i.e. Workplace Based Assessments, Evaluations etc).

The second one is about Teaching Attendance (i.e. Taught Programme, Specialty-Specific Learning Activities and Study Days)

ASSESSMENT APPENDIX

Workplace-Based Assessment and Evaluations

The expression "workplace-based assessments" (WBA) defines all the assessments used to evaluate trainees' daily clinical practices employed in their work setting. It is primarily based on the observation of trainees' performance by trainers. Each observation is followed by a trainer's feedback, with the intent of fostering reflective practice.

Relevance of Feedback for WBA

Although "assessment" is the keyword in WBA, it is necessary to acknowledge that feedback is an integral part and complementary component of WBA. The main purpose of WBA is to provide specific feedback for trainees. Such feedback is expected to be:

- **Frequent**: the opportunities to provide feedback are preferably given by directly observed practice, but also by indirectly observed activities. Feedback is expected to be frequent and should concern a low-stake event. Rather than being an assessor, the trainer is an observer who is asked to provide feedback in the context of the training opportunity presented at that moment.
- **Timely**: preferably, the feedback should be a direct conversation between trainer and trainee in a timeframe close to the training event. The trainee should then record the feedback on ePortfolio in a timely manner.
- **Constructive**: the recorded feedback would inform both trainee's practice for future performance and committees for evaluations. Hence, feedback should provide trainees with behavioural guidance on how to improve performance and give committees the context that leads to a rating, so that progression or remediation decisions can be made.
- **Actionable:** to improve performance and foster behavioural change, feedback should include practical and contextualised examples of both Trainee's strengths and areas for improvement. Based on these examples, it is necessary to outline a realistic action plan to direct the Trainee towards remediation/improvement.

Types of WBAs in use at RCPI

There is a variety of WBAs used in medical education. They can be categorised into three main groups: *Observation of performance*; *Discussion of clinical cases*; and *Feedback.*

As WBAs at RCPI we use *Observation of performance* via PMAT; *Discussion of clinical/project cases* via PbD; *Feedback* via Feedback Opportunity.

Mandatory Evaluations are bound to specific events or times of the training year, for these at RCPI we use: Quarterly Evaluation/End of Post Evaluation; End of Year Evaluation; Penultimate Year Evaluation; Final Year Evaluation.

Recording WBAs on ePortfolio

It is expected that WBAs are logged on an electronic portfolio. Every trainee has access to an individual ePortfolio where they must record all their assessments, including WBAs. By recording assessments on this platform, ePortfolio serves both the function to provide an individual record of the assessments and to track trainees' progression.

Formative and Summative Feedback

The Trainee can record any WBA either as formative or summative with the exception of the *Mandatory Evaluations* (Quarterly/End of Post, End of Year, Penultimate Year, Final Year evaluations).
If the WBA is logged as formative, the trainee can retain the feedback on record, but this will not be visible to an assessment panel, and it will not count towards progression.
If the WBA is logged as summative, it will be regularly recorded and it will be fully visible to assessment panels, counting towards progression.

WORKPLACE-BASED ASSESSMENTS	
PMAT *Pharmaceutical Medicine Assessment Tool*	The PMAT is an assessment that focuses on the competencies that trainees in pharmaceutical medicine demonstrate in their everyday encounters with projects and colleagues. Competences can be defined as those behavioural characteristics which lead to outstanding or superior performance in a job role. They complement traditional skills and knowledge in representing deeper seated qualities, including behaviours and values which can contribute to the difference between average and outstanding performance. They are dynamic and interact with each other and are well suited to measurement of progress over time in personal learning and development. The competencies described in the PMAT are all interlinked and fall into five general categories: • Understanding the environment (analytical thinking) Working with others (communication & presentation skills; teamwork; negotiation skills), Personal effectiveness (building expertise), Delivery (concern for quality; planning and prioritisation; flexibility and initiative; change management), and Managing performance (people management skills; leadership) The PMAT is an observation or 'snapshot' of a trainee interaction with project or colleagues. It involves direct observation by an assessor of trainees' performance in real work situations and is designed to assess a wide range of competences appropriate for the practising pharmaceutical physician. Not all competences can be assessed on a single occasion.
PbD *Project based Discussion*	A PbD assesses the performance of a trainee in the management of a project to provide an indication of competence in areas such as reasoning, decision-making and application of medical knowledge in relation to project goals and outcomes. It also serves as a method to document conversations about and presentations of projects by trainees. The PbD should include discussion about a written record (such as written plans, progress reports, final reports). A typical encounter might be around the presentation of an interim project update to the project team. The PbD is a structured narrative-based instrument for assessment of areas of application, learning, competency, and performance related to non-standard project(s) being undertaken by the trainee at a point in time. It can be linked closely with associated PMAT assessment(s).
Feedback Opportunity	Designed to record as much feedback as possible. It is based on observation of the trainees in any clinical and/or non-clinical task. Feedback can be provided by anyone observing the trainee (peer, other supervisors, healthcare staff, juniors). It is possible to turn the feedback into an assessment (PMAT, PbD)
MANDATORY EVALUATIONS	
QE *Quarterly Evaluation*	As the name suggests, the Quarterly Evaluation recurs four times in the academic year, once every academic quarter (every three months). It frequently happens that a Quarterly Evaluation coincides with the end of a post, in which case the Quarterly Evaluation will be substituted by completing an End of Post Evaluation. In this sense the two evaluations are interchangeable, and they can be completed using the same form on ePortfolio. However, if the trainee will remain in the same post at the end of the quarter, it will be necessary to complete a Quarterly Evaluation. Similarly, if the end of a post does not coincide with the end of a quarter, it will be necessary to complete an End of Post Evaluation to assess the end of a post. This means that for every specialty and level of training, a minimum of four Quarterly Evaluation and/or End of Post Evaluation will be completed in an academic year as a mandatory requirement.
EOP *End of Post Evaluation*	
EOYA *End of Year Evaluation*	The End of Year Evaluation occurs once a year and involves the attendance of an evaluation panel composed of the National Specialty Directors (NSDs); the Specialty Coordinator attends too, to keep records of and facilitate the meeting. The assigned trainer is not supposed to attend this meeting unless there is a valid reason to do so. These meetings are scheduled by the respective Specialty Coordinators and happen sometime before the end of the academic year (between April and June).
PYE *Penultimate Year Evaluation*	The Penultimate Year Evaluation occurs in place of the End of Year Evaluation, in the year before the last year of training. It involves the attendance of an evaluation panel composed of the National Specialty Directors (NSDs) and an External Member who is a recognised expert in the Specialty outside of Ireland; the Specialty Coordinator attends too, to keep records of and facilitate the meeting. The assigned trainer is not supposed to attend this meeting unless there is a valid reason to do so.
FYE *Final Year Evaluation*	In the last year of training, the End of Year Evaluation is conventionally called Final Year Evaluation, however, its organisation is the same as an End of Year Evaluation.

TEACHING APPENDIX

RCPI Taught Programme

The new RCPI Taught Programme consists of a series of modular elements spread across the years of training.

Delivery will be a combination of self-paced online material, live virtual tutorials, and in-person workshops, all accessible in one area on the RCPI's virtual learning environment (VLE), RCPI Brightspace.

The live virtual tutorials will be delivered by Tutors related to this specialty and they will use specialty-specific examples throughout each tutorial. Trainees will be assigned to a tutorial group and will remain with their tutorial group for the duration of HST.

Trainees will receive their induction content and timetable ahead of their start date on HST. Trainees must plan the time to complete their requirements and must be supported with the allocation of study leave or appropriate rostering.

As the HST Taught Programme is a mandatory component of HST, it is important that Trainees are released from service to attend the Virtual Tutorials and, where possible facilitated with the use of teaching space in the hospital.

Specialty-Specific Learning Activities (Courses & Workshops)

Trainees will also complete specialty-specific courses and/or workshops as part of the programme.

Trainees should always refer to their training Curriculum for a full list of requirements for their HST programme. When not sure, Trainees should contact their Programme Coordinator.

Study Days

Study days vary from year to year, they comprise a rolling schedule of pharmaceutical medicine educational days and national/international events selected for their relevance to the HST Curriculum.

Trainees are expected to attend the majority of the study days available and **at least 6 per training year**.

Pharmaceutical Medicine Teaching Attendance Requirements