

**RCPI***online*

The Royal College of Physicians of Ireland

**THE IRISH COMMITTEE ON  
HIGHER MEDICAL TRAINING**

**CURRICULUM FOR HIGHER  
SPECIALIST TRAINING**

**IN**

**CLINICAL PHARMACOLOGY  
&  
THERAPEUTICS**

**OCTOBER, 2002.**

# **CLINICAL PHARMACOLOGY AND THERAPEUTICS**

## **ENTRY REQUIREMENTS**

Applicants for Higher Medical Training (HMT) must have completed a minimum of 2 years General Professional Training (GPT) in approved posts and obtained the MRCP (I) or (UK). A period of experience in Clinical Pharmacology and Therapeutics at Senior House Officer grade is considered desirable before entry to HMT, although not essential. Assuming that GPT is divided into 4 periods of 6 months, all 4 should involve contact with patients, at least 3 should be connected with acute medical problems, and at least 2 should involve acute unselected medical intake.

Graduates of non-Irish/UK medical schools without the MRCPI or (UK) who compete for HMT posts must provide evidence of knowledge, training and qualifications equivalent to MRCPI or (UK) standard, particularly in the care of acute medical conditions.

## **DURATION AND ORGANISATION OF TRAINING**

The minimum duration of HMT in Clinical Pharmacology and Therapeutics is 4 years. Those who wish to obtain dual certification e.g. to include General Internal Medicine (GIM), will require at least one further year in training. The first year of the joint programme will comprise experience in General (Internal) Medicine, but should include early experience in Clinical Pharmacology and Therapeutics i.e. half-day/ week equivalent. Because experience in clinical and laboratory research is fundamental to the specialist in Clinical Pharmacology and Therapeutics, two of the remaining four years will be spent in supervised research. The remaining two years must be spent in a District General Hospital (DGH) or a teaching hospital with DGH facilities, undergoing training for equal periods in General (Internal) Medicine and Clinical Pharmacology and Therapeutics. Trainees intending to practise in Clinical Pharmacology and Therapeutics and a specialty other than General (Internal) Medicine, should seek guidance from ICHMT on the duration and organisation of their training.

HMT will provide experience in both teaching hospitals or other major centres with academic activity, and in General Hospital. The posts within the programme to which a trainee is appointed will have named consultant Trainers. In addition, one consultant will act as a Programme Director, who will co-ordinate the training and report to the National Specialty Director appointed by the ICHMT.

## **ASSESSMENTS AND TRAINING RECORDS**

Assessment of trainees will be based upon a standard format of Annual Review. The recommendations of the National Specialty Director of Higher Medical Training in Clinical Pharmacology and of the Trainers will be submitted to the ICHMT, which through the RCPI retains the final responsibility for advising the Medical Council on the Satisfactory Completion of Specialist Training.

A **Training Record** or log book will be maintained by the trainee. It will be counter signed **quarterly** by the relevant Trainer (educational supervisor) and may be used to confirm the satisfactory fulfilment of the required training experience and the acquisition of competence in areas enumerated in the Curriculum. The Training Record will remain the property of the trainee and must be produced at the Annual Assessment and for the final ICHMT decision on certification.

At least one of the Annual Reviews, usually towards the end of the penultimate year of training, will involve external assessment. It will be the responsibility of the Assessment Panel to indicate where specific deficiencies in the trainee's experience exist, and if required, remedial action will be recommended. In these circumstances, the recommendation to issue a Certificate of Satisfactory Completion of Specialist Training (CSCST) will be withheld until the assessors are satisfied that the remedial actions have been successful undertaken.

## **RESEARCH, ACADEMIC AND OTHER OUT-OF-PROGRAMME APPOINTMENTS**

The period of research in Clinical Pharmacology and Therapeutics will be two years. This is because the specialist in Clinical Pharmacology and Therapeutics is expected to guide and direct the clinical assessment of drugs, and requires a broader experience of the investigation methods used in pharmacological research. Necessary skills for the design and ethical conduct of drug investigation in accordance with Good Clinical and Laboratory Practice are best acquired through practical experience of pharmacokinetic, interaction and dose-ranging studies, clinical trials, and pharmaco-vigilance studies. These skills are frequently sought by Local Research Ethics Committees for the effective execution of their function.

Approval of training outwith Ireland and the United Kingdom will only be considered if evidence of the nature of the training has been submitted in advance through the Dean of HMT to the ICHMT. This will normally require a written statement from the department concerned and written support from the trainee's own programme director. Overseas training may be clinical or in research and will be recognised for up to a maximum of two years and may consist of clinical training, or include research (for which a maximum of one year credit is allowed).

Academic posts are perfectly acceptable for consideration for inclusion in HMT provided prospective approval has been obtained.

## **Clinical Experience**

See curriculum for Higher Medical Training in General (Internal) Medicine.

The trainee should take an active part in the local inpatient and outpatient consultation service in Clinical Pharmacology and Therapeutics, and in local approaches to rational and cost-effective prescribing.

## **Management Training**

This should include awareness of the organisation and function of the Health Service, and of the relation between community and hospital services (particularly in the area of prescribing); an understanding of drug and clinical budgeting, personnel management, medical staff employment and complaints procedures; and acquisition of skills of interviewing, written communication, and committee participation.

## **Medical Audit**

The trainee should attend and contribute to regular peer-group audit meetings at which clinical practice and drug therapy are exposed to critical scrutiny.

## **Industrial Experience**

Some trainees seeking accreditation in Clinical Pharmacology and Therapeutics may be planning a career as pharmaceutical physicians in the Pharmaceutical Industry. The entry criteria and duration of HMT will be the same for these trainees, though approved experience in the Pharmaceutical Industry can be counted towards the overall requirement, giving up to one year's credit.

# **CURRICULUM**

## **Drug Action in Human Subjects**

A clinical pharmacologist should have a broad knowledge and understanding of the consequences of administering drugs to humans. This should include experience of the administration of drugs in one or more disease states; knowledge and experience of the consequences of giving drugs to normal volunteers; and knowledge of the action of drugs at a cellular and molecular level. The extent to which training in each of these areas is provided during professional training will depend on the previous experience in the trainee. For example, a trainee who already has an undergraduate degree in pharmacology or a closely related area would have different requirements from the one who does not.

## **Clinical Pharmacokinetics**

During the period of training a clinical pharmacologist should acquire knowledge of the different routes of drug administration together with methods of measuring the time course of drugs and their metabolites in blood and other body fluids. At least a basic understanding of different analytical techniques for measuring drug concentration should be acquired, and all clinical pharmacologists should understand the methods of pharmacokinetic analysis and the interpretation of the results.

## **Theory and Practice of Statistics and Experiment Design**

During the period of training, a clinical pharmacologists should demonstrate an understanding of the principles underlying the design of clinical trials and of the appropriate use of statistics in analysing data. In addition trainees should be personally involved under supervision in the design of at least one clinical trial or normal volunteer study. It is recommended that trainees understand how to interpret preclinical pharmacological and toxicological studies; the design and conduct of Phase I clinical studies of new drugs and the rational and cost-effective use of medicines.

## **Evaluation of Scientific Literature**

The trainee should be familiar in all methods of literature searching and should have supervised experience of the evaluation of scientific papers (eg through a Journal club).

## **Drug and Therapeutics Committee**

The trainee should become familiar with the functions of a Drug and Therapeutics Committee and the role of a clinical pharmacologist in influencing prescribing policy and the use of drugs.

## **Drug Formularies**

A working knowledge of Drug Formularies should be obtained with an understanding of the disparate requirements of Formularies at local, national and international level.

## **Communication and Educational Skills**

Teaching is a very important part of the professional service offered by clinical pharmacologists. Trainees should therefore obtain supervised experience in undergraduate and postgraduate teaching and if appropriate, should attend courses designed to improve teaching skills.

## **Recommended Experience**

The trainee should become familiar with:

- the design and conduct of Phase II and III clinical studies of new drugs
- the management, detection and reporting of adverse drug reactions
- the treatment of drug overdose
- the epidemiological approach to drug usage, efficacy and toxicity
- therapeutic drug monitoring
- the regulatory requirements covering the development and licensing of new medicines
- the role and function of a local Research Ethics Committee (by attendance as an observer)

## TRAINING PROGRAMMES

There is no European Board for Clinical Pharmacology. The majority of trainees will spend some time particularly in the United Kingdom and it is anticipated that such experience could be integrated into the training programme. Similarly experience in the pharmaceutical industry or a Drug Regulation Agency may be encompassed depending on the intended career path of the trainee.

Three programmes have been approved by the Irish clinical pharmacologists. At present those based at Beaumont Hospital and Mercy Hospital (Cork) do not provided for all obligatory experience and trainees need to gain that experience in another centre or in the United Kingdom. Rotations, depending on the wishes and career aspiration of the trainee, between Centres in Ireland are encouraged and will where possible be facilitated.

Programme 1: Information	TCD/St. James's Hospital/National Medicines Centre, Dublin (Professor J. Feely, Dr. M. Barry) Full programme – details next page.
2:	UCC/Mercy/Bon Secours Hospitals, Cork (Professor M. Murphy, Dr. P. Leary, Dr. B. Buckley)
3:	RCSI/Beaumont Dublin (Professor D. Fitzgerald)

## Specialist Registrar Training Post – Clinical Pharmacology

	Beaumont Hospital	St. James's Hospital	Mercy Hospital, Cork
<b>Total number of beds</b>	750	760	
<b>National Specialty Profile</b>	Neurosciences/ Nephrology & Renal Transplantation	National Medicines & Information Centre, HIV/AIDS, Bone Marrow, Plastic Surgery, Burns Unit	
<b>Consultants (Clin Pharm) Comhairle approved No. Associated part/time</b>		2 1	
<b>Number beds GIM</b>		9	
<b>Number of Clinical Pharmacology 5 day beds</b>			
<b>Consultant Supervised Clinics Number/week</b>		3/week	
<b>G(I)M General (Internal) Medicine</b>		1/week	
<b>Hypertension</b>		1/week	
<b>Cardiology</b>		-	
<b>Other</b>		Lipid Clinic	
<b>Clinical Trials Unit – No. Beds</b>		3	
<b>Phase II/III Trials – No./Year</b>		2-6	
<b>Pharmacoeconomics</b>		Centre	
<b>Drug Information</b>		Centre	
<b>Drug Regulation</b>		Consultative	
<b>Analytical Laboratory facilities (drugs)</b>		✓	
<b>Therapeutic Drug Monitoring</b>		Consultation	
<b>Pharmacovigilance Function</b>		✓	
<b>Pharmacoepidemiology</b>		✓	
<b>Ethics Committee involvement</b>		✓	
<b>Drugs and Ther/Formulary Committee involvement</b>		✓	
<b>Management of Drug overdose – No./Year</b>		70	
<b>University Affiliation</b>	RCSI	TCD	UCC