

Assessment Blueprint for Clinical Pharmacology & Therapeutics

Curriculum Area/Competence		Knowledge Based Exam	Mini-CEX	DOPS	MSF	CBD	Patient Survey
Objective 1. The trainee will be able to undertake and interpret early phase studies of drug action in humans.		√					
K	Describe theories of drug-receptor interactions and the related concepts of agonists, antagonists, structure action relations, dose response relations, pharmacodynamics (PD), pharmacokinetics (PK), PK/PD interrelations, efficacy and potency.	√					
	Understand the meanings of surrogate endpoints, tolerability and adverse effects.	√					
	Demonstrate knowledge of the principles of 'first into man' studies.	√					
	Demonstrate knowledge, and understand the limitations, of pre-clinical studies in the early phase human testing of biological products.	√					
S	Write trial protocols.		√				
	Write and submit REC submissions		√				
	Able to recruit subjects for studies and obtain valid informed consent.		√		√		
	Perform PD and PK studies in human volunteers (including nulation and other skills relevant to their clinical area of expertise).		√				
	Measure end points reliably.			√			
	Record data accurately.			√			
	Analyse data including risk-benefit analysis and dose determination for definitive phase-3 studies.		√				
	Identify, review and analyse relevant literature.		√				
	Draft papers for publication.		√				
	Communicate with co-workers and agree a final manuscript for submission.		√				

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	Demonstrate communication skills in effective presentation of a paper at scientific meetings			√			
AB	Consult appropriately.				√		
	Recognise the primacy of subject safety.				√		
	Appreciate the need for meticulous record keeping and research governance.		√				
	Appreciate the importance of communicating research data orally and in written form and is diligent in writing and rehearsal.		√				
Objective 2. The trainee will be able to use pharmacokinetic principles to optimise drug administration and drug effect.							
K	Describe the principles of: correct choice of route of administration, absorption of drugs, metabolism and excretion of drugs, interpretation of drug concentration in body fluids, pharmacokinetics, drug assay, PK-modelling, pharmacogenetics, PK-based drug interaction, personalised medicine.	√					
	Demonstrate knowledge of common analytical methods and their limitations.	√					
	Demonstrate knowledge of good laboratory practice (GLP).	√					
S	Construct and adjust dose regimens correctly					√	
	Negotiate an acceptable regimen with the patient where appropriate					√	√
AB	Recognise the need for individualisation of therapy where necessary.					√	
	Recognise the importance of taking responsibility for repeated observation and ongoing patient follow-up on the wards, and for volunteer follow-up during clinical investigation.					√	

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	Respect patient/ subject autonomy						√
	Recognise the importance of concordance.	√				√	
Objective 3. The trainee will be able to use drugs rationally and cost-effectively.							
K	Demonstrate knowledge of the mechanisms of action and modes of use of common therapeutic drugs.	√					
	Demonstrate knowledge of sources of individual variation including genetic, age- and gender- related (including pregnancy and lactation), and other sources of individual variation especially co-existing renal hepatic and other disease and drug interaction both beneficial and adverse.	√					
	Explain the roles of National and European bodies including the medicines and medical devices health regulatory agency (MHRA), European medicines evaluation agency (EMA), national institute for clinical excellence (NICE) in ensuring rational and cost effective use of medicines.	√					
	Demonstrate knowledge of non-physician prescribing, including patient group directives (PGD) and dependent and independent prescribing.	√					
S	Communicate effectively with individual patients, clinical colleagues and in committee.				√		√
	Select drugs and dose regimens rationally based on individual factors.					√	
	Develop prescribing policies, formularies and guidelines.					√	
	Evaluate guidelines on medicines utilisation in the context of D&T committees.					√	
	.Write guidelines on medicines management for evaluation by D&T committees.					√	
	Make effective submissions to formulary committees for new drugs					√	

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	Audit drug utilisation					√	
AB	Prescribe with due regard to general knowledge, as specified combined with specific patient related information relating to demographic characteristics, drug history and individual preference.					√	
	Respect the varied expertise of drug and therapeutics committee members with diverse skills and backgrounds.				√		
	Participate in decision making/consensus building in the context of D&T committee.				√		
Objective 4. The trainee will be able to critically evaluate literature relevant to CPT including basic pharmacology, toxicology and phase I, II, III and IV clinical trials and meta-analysis.							
K	Demonstrate knowledge of basic pharmacology and clinical medicine at levels of competency defined in the CPT application to PMETB.	√					
	Know how to report misleading advertising claims to MHRA and ABPI.	√					
S	Critically analyse papers regarding rationale, cogency, experimental design, analytical methodology, method of analysis, potential sources of bias, confounding, conflict of interest, appropriateness of discussion, validity of conclusions.		√				
	Critically analyse advertising claims made for medicinal products.		√				
	Uses electronic databases (eg Medline, Embase, Toxbase, Cochrane).		√				
AB	Respect ethical principles underlying peer review.		√				
	Participate in peer review.		√				

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	Evaluate expert reviews (eg NICE).					√	
	Communicate effectively in journal clubs, drug and therapeutics and audit committee meetings			√			
Objective 5. The trainee will be able to select prospectively appropriate statistical methods for planned experiments (including clinical trials), perform such analyses, and interpret the resulting statistical output.							
K	Describe the sources of biological variation and explain the principles involved in quantifying this.	√					
	Describe common parametric and non-parametric tests including chi-squared, t-tests, ANOVA, Bonferoni correction and least squares and Spearman rank regression	√					
	Analyse critically the pros and cons of sequential analysis.	√					
S	Consult effectively with statisticians during the planning stage of complex experimental studies.		√				
	Interpret P values and confidence intervals (CI) including CI of differences in the case of negative trials.		√				
	Explain the biological meaning of non-inferiority trials.		√				
	Use a modern statistics package		√				
AB	Possess a self-critical attitude that only accepts an outcome that is understood.		√				
	Demonstrate a willingness to consult appropriately.		√				
	Undertake work in a patient and meticulous manner.		√				

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Objective 6. The trainee will be able to design clinical trials, including phase 3 studies, and contribute to their execution and dissemination.							
K	Describe different trial designs.	√					
	Demonstrate knowledge of the principles of controlled experiments, randomisation, use of placebo and blinding.	√					
	Describe principles underpinning ethics of research on human subjects including duties, rights and utilitarianism.	√					
	Demonstrate knowledge of good clinical practice (GCP).	√					
S	Select a trial design appropriate to the research question.		√				
	Write an REC application.		√				
	Justify a research proposal in terms that are understood by the lay members of an REC.		√				
	Able to recruit research subjects.		√				
	Screen potential subjects for inclusion/exclusion criteria.		√				
	Obtain valid informed consent			√			
	Arrange visits of research subject to clinical laboratory or research clinic		√				
	Perform and/ or supervise clinical measurements.		√				
	Keep records to the standard required by GCP.		√				
AB	Contribute to writing papers and reporting findings by oral and poster presentations at meetings		√				
	Maintain absolute honesty.				√		

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	Recognises need to have ultimate control over the right to publish or otherwise disseminate resulting information.		√				
	Maintain meticulous attention to detail.		√				
	Recognise the primacy of safety of the subject		√				
	Maintain a professional relationship with study sponsors and their employees (CROs etc).				√		
Objective 7. The trainee will be able to anticipate (and hence minimise), detect, manage, report and analyse adverse drug reactions (ADR).							
K	Demonstrate knowledge of important (common and/or severe) adverse effects of drugs used in their area of clinical practice	√					
	Demonstrate the knowledge of the mechanisms whereby drugs cause ADR	√					
	Demonstrate knowledge of common clinical presentations of ADR	√					
	Demonstrate knowledge of appropriate management of ADR	√					
	Explain how ADR are identified and reported.	√					
	Explain the classification of ADR.	√					
S	Manage common and serious ADR, including anaphylaxis, appropriately.					√	
	Use printed and electronic resources to identify unusual or uncertain ADR.					√	
	Analyse post marketing surveillance studies critically					√	
	Report suspected ADR appropriately.					√	
AB	Alert to the possibility that clinical events are drug-related.					√	
	Prepared to share information and suspicions without consideration of perceived future aggrandisement or gain.				√		
	Consult with colleagues over judgements such as risk/benefit of rechallenge.				√		

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	Can assess the quality of post marketing surveillance and differentiate from marketing device					√	
Objective 8. The trainee will be able to describe and influence what determines the pattern of use of medicines in populations.							
K	Identify factors that affect drug utilisation including effects of: social class, ethnicity, nationality (especially within Europe), economic status, co-morbidity, age and gender (including pregnancy and lactation).	√					
	Demonstrate knowledge of factors affecting public perception of drugs and their use in treating and preventing disease, including effects of media on medicines utilisation.	√					
	Describe the role of the pharmaceutical industry in the public perception of drug use.	√					
	Explain the role of government in licensing, pricing and cost-benefit analysis underpinning drug availability in the NHS, and the legislation that underpins these.	√					
	Explain the role of local groups (D&T committees and formulary committees) in defining the availability of medicines in a local health context.	√					
S	Apply this knowledge in individual patient practice and in drafting management guidelines					√	
	Interact effectively with the media as well as in committees.				√		
	Handle potential conflicts of interest appropriately				√		
AB	Respect ethnic diversity.				√		√
	Respect individual autonomy.				√		√
	Contribute to public education about drugs and their utilisation.					√	√
	Respect the law relating to medicines in the UK and understand its main exclusions (eg the Medicines Act 1968).					√	

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	Engage in the reform of current practice in the UK and Europe (e.g. via participation in public consultations on medicines utilisation initiated by MHRA or by NICE).					√	
Objective 9. The trainee will understand the principles of research ethics and contribute to the process by which ethical research in human subjects is ensured.							
K	Identify ethical principles on which human research rests.	√					
	Explain how decisions are made when ethical principles conflict with one another.	√					
	Justify the constitution/ membership of research ethics committees (REC).	√					
	Demonstrate knowledge in appropriate terms of reference of REC.	√					
	Demonstrate knowledge in international guidance on ethical research in humans (eg the Declaration of Helsinki and ICH guidelines).	√					
	Demonstrate knowledge of the legal framework in which REC operate in Europe and the UK	√					
S	Analyse REC applications and information documents.					√	
	Ask pertinent questions of applicants and fellow committee members including specialists such as lawyers and statisticians.			√			
	Communicate effectively in an REC.				√		
AB	Respect confidentiality of information.			√			
	Conscientiously read submissions to REC of which the trainee should be a member					√	
	Contribute to discussion in committee.			√			
	Be open minded and prepared to change a view in light of discussion.				√		

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Objective 10. The trainee will be able to advise on cases of overdose or poisoning, and to manage such cases as are relevant to their clinical speciality (e.g. children for paediatricians).							
K	Demonstrate knowledge of mechanisms of action of important poisons, including therapeutic drugs commonly taken accidentally or deliberately in overdose.	√					
	Demonstrate knowledge of strategies for management of poisoned patients including: protection of staff and other patients, decontamination, resuscitation, monitoring, antidotes including for digoxin, iron, cyanide and cholinesterase inhibitors.	√					
S	Access information effectively, including via the National Poisons Units.					√	
	Access and keep up to date with National Guidance on chemical attack.					√	
	Develop diagnostic skills relevant to the epidemiological context of chemical attack.					√	
	Maintain up to date qualifications in resuscitation skills						
	Possess skills in managing overdose with paracetamol, aspirin, opioids, benzodiazepines and tricyclics.						√
AB	Prepares prudently in the face of possible chemical incident, protecting self and other staff and avoiding self-contamination.			√			
	Once prepared, accept necessary residual risk in order to care for poisoned patients.			√			
	Respect patients with behavioural and psychiatric problems, and consult appropriately with colleagues in provision of psychiatric support.				√		√