CORE CLINICAL PHARMACOLOGY TRAINING & KNOWLEDGE BASE

1. Study days will be modular and bimonthly.
2. All 18 modules will be completed over 3 years.
3. Sessions will run from 10am to 4pm (approximately)
4. Sessions will rotate through all North West partner venues
5. Sessions will be open to all trainees: MRC fellows as well as CPT trainees etc.
6. Additional modules may be run as necessary
7. The order and content of modules will vary according to the collective development needs and wishes of the trainees.

Module	Module Title	Topics to be covered
1.	Drug Action in Humans	• Receptors, agonists and antagonists • Structure-activity relationships • Dose-response curves • Efficacy and potency • Principles of pharmacodynamic studies and surrogate endpoints
2.	Principles of Pharmacokinetics 1	• Absorption and distribution • Metabolism and excretion • Concepts—half-life, volume of distribution, clearance • Common analytical methods and their limitations (including GLP) • Individual variability including effects of disease
3.	Principles of Pharmacokinetics 2	• Mathematical concepts • PK-modelling • Population pharmacokinetics • Bioavailability and bioequivalence • Pharmacokinetics practical exercise
4.	Principles of Statistics* *statistical considerations to be incorporated throughout rest of programme as appropriate	• Sources of biological variation • Common parametric and nonparametric tests • Sample size determination • Probability and significance • Interpretation of study deign, analysis and results.
5.	Clinical Trial Design	• Applicability of pharmacokinetics to dosage regimen and study design • Planning of clinical trial programme—use of preclinical and phase 1 data • Study types and designs • Populations for exploratory studies –healthy volunteers and patients • Clinical trial design practical exercise
6.	Early Phase Clinical Trials 1	• Preclinical safety testing—toxicology and safety pharmacology. • Use of investigator brochure • Relationship between animal and human pharmacology • Calculation of the starting dose: NOAEL and MABEL • Dose –escalation studies: single ascending dose/multi ascending dose

Module	Module Title	Topics to be covered
7	Early Phase Clinical Trials 2	• Proof of concept & safety studies • Drug-drug interaction studies • Drug-food interaction studies • Use of biomarkers and pharmacodynamic endpoints, dose-response • Within-trial decisions, data management, extraction and manipulation
8.	Late Phase Clinical Trials	• Phase III trial study design • Analysis of efficacy endpoints • Studies in different populations (renal and liver impairment) • Options for data collection (manual and electronic) • Contractual arrangements with investigators and contract research organisations
9	New and Emerging Technologies	• Pharmacogenomics • Proteomics, transcriptomics and metabalomics • Biomarker discovery and validation • Next generation sequencing • Systems biology
10	Adverse Drug Reactions and Pharmacovigilance	• Adverse Events and SAEs - collection, reporting, coding, ICH and CIOMS • Mechanisms, predisposing factors in health and disease • AE monitoring, post-marketing surveillance, spontaneous reporting, PSURs • Databases and signal generation • Benefit-risk assessment and issue and crisis management
11	Research Ethics Workshop 1	• Guidance on ethical research in humans (e.g. The Declaration of Helsinki and ICH) • The legal framework in which REC operate in Europe and the UK • Constitution/membership of research ethics committees (REC) • Appropriate terms of reference of REC • Informed consent practical 1
12.	Research Ethics Workshop 2	• Ethical considerations for Phase I studies • Drafting submission of informed consent documents • Confidentiality and data protection • Indemnity and insurance • Informed consent practical 2
13.	Medicines and Clinical Trials Regulation	• The general principles of medicines regulation • Medicines regulation in UK, EU, USA and Japan • Clinical trials regulation in the UK • The MHRA Phase I Accreditation Scheme • The role and responsibilities of the principle investigator

Module	Module Title	Topics to be covered
14.	Rational and Cost-Effective Drug Use	• Factors that affect drug utilisation • Role of government in licensing, pricing and cost-benefit analysis • Pharmacoeconomics • The role of NICE • National and local formularies
15.	The Healthcare Marketplace	• Principles of health economics and quality of life • Pharmacoepidemiology • Marketing structure and competition, and price negotiations • Product information, advertising and claims • Measurement of healthcare, government policy and third-party reimbursement
16.	Discovery of New Medicines	• Disease target identification and selection • Patenting new active substances • Receptor-based approaches, enzyme inhibitors, genomics, proteomics • Lead optimisation and candidate selection of molecules for investigation. • In vitro and in vivo testing of new compounds
17.	The Role of the Pharmaceutical Industry	• Activities and contribution of International Conference on Harmonisation • Regulatory submissions and quality control • SmPCs and PILs • Dear Dr letters and withdrawal of products • Codes of practice, industry self regulation, advertising
18.	Clinical Pharmacology and Medical Emergencies	• Risk management • Phase I clinical trials and medical emergencies • Anaphylaxis: molecular and clinical considerations • Drug induced liver injury • Case-based discussions