SYLLABUS DIPLOMA AND CERTIFICATE IN HUMAN PHARMACOLOGY

Science

1. Clinical Pharmacology and Therapeutics. Major therapeutic small molecule drug classes and their mechanisms of action. Monoclonal antibodies and other biologicals. Agonists, partial agonists, antagonists, dose-concentration-response. Factors affecting therapeutic outcome.

2. The molecular basis of drug action. Receptor pharmacology, signal transduction, second messengers, enzymes, regulatory proteins, transcription factors, cellular sites of drug action, ion channels.

3. Integration of information. Sources and critical review of scientific literature; evaluation of benefit / risk based on preclinical / early clinical data.

Guidelines

4. Guidelines for human pharmacology studies. Content of guidelines concerning the conduct of non-patient and patient volunteer studies including the elderly and women (e.g ABPI Guidelines for Phase I clinical trials, Guideline on strategies to identify and mitigate risks for First in Human clinical trials with Investigational Medicinal Products, EMEA/CHMP/SWP/294648/2007)

Study Design

5. Principles of Study Design. Advantages and disadvantages of different types of study design; specific study designs for first administrations of single and multiple doses (including methods for selection of starting dose, dose increments, maximum doses, stopping rules, details of study conduct including interim reviews); drug interactions; bioequivalence and bioavailability; demographic factors; organ failure.

Study Facilities and Conduct

6. Facilities, Equipment and Personnel. Standards for clinical facilities; guidelines, resuscitation equipment; qualifications and experience of physicians, nursing staff and non clinical scientific staff; key issues in the organisation and administration of research units for the conduct of studies in healthy non-patient volunteers.

7. Selection of Non-Patient Volunteers*. Identification of the healthy volunteer; screening for significant conditions; laboratory testing; cardiorespiratory assessment; allergy risks; psychiatric assessment; screening for metabolic phenotype; detection of asymptomatic conditions; avoidance of multiple study participation; recruitment of volunteers; hazards of drugs of abuse; the issues surrounding studies in women of child bearing potential.

8. Studies in Patient Volunteers*. Facilities; types of study, issues specific to patient studies; selection of patient volunteers; avoidance of multiple study participation.

9. Clinical Conduct of Studies*. Responsibilities of the PI, other investigators, nursing staff and non clinical scientific staff; potential `hazards' of participation for volunteers; follow-up of volunteers; non-drug influences on study outcome, monitoring of safety including cardiorespiratory, laboratory, drug specific measurements.

10. Routes of Administration. The safety, scientific and technical issues relevant to different routes of administration including oral, parenteral, topical, inhaled and modified release.

PK, PD, Data Analysis, Presentation and Interpretation

11. Pharmacokinetics. Principles of PK and ADME, importance of pharmacogenetics, objectives of and issues to be considered in the design of PK studies, presentation and interpretation of data, principles and performance of different bioanalytical techniques.

12. Pharmacodynamics. Principles underlying use of biomarkers, PD measurements, surrogates for clinical endpoints, objectives of and issues to be considered in the design of PD studies, commonly used biomarkers and surrogates for desired and undesired effects in different therapeutic areas, application of imaging techniques in the assessment of drug action.

13. Proof of Concept. Definitions of Proof of Concept (PoC), Benefit / Risk Balance, Use of PK/PD.

14. Principles of Medical Statistics. Hypothesis testing and hypothesis generation; within- and between-subject variation; power calculations; data summarising and display.

Pharmaceuticals with Particular Requirements

15. Biopharmaceuticals. The specific issues relating to early development of biopharmaceuticals, biopharmaceutical manufacture and formulations, particular issues relating to agonists, extrapolation of animal data to man, cross reactivity, toxicological evaluation, early clinical evaluation, determination of starting dose and duration of effect.

16. Radioactive molecules. Radiation protection in biological research. The specific legal requirements, facilities and radiation protection measures relating to administration of radiopharmaceuticals for mass balance, imaging and other studies including requirements of the Administration of Radioactive Chemicals Advisory Committee.

17. Gene therapies. The specific issues relating to the introduction of genetic material into human somatic cells for therapeutic, prophylactic or diagnostic purposes e.g. genetically modified viral vectors, naked DNA injection and anti-sense techniques. Familiarity with Gene Therapy Advisory Committee guidelines.

Safety

18. Animal Safety Assessments for Initial Studies in Man. Design, conduct and interpretation of general and reproductive toxicology studies, genotoxicity and safety pharmacology, the use of preclinical pharmacological and pharmacokinetic assessments; principles of human risk assessment from animal toxicology studies; importance of toxicokinetics; inter-species scaling; differences between man and animals.

19. Adverse Events*. Methodology for collection, mechanisms, types of adverse events, drug allergy, the extent of variation in normality; principles of event attribution; actions required and influence of adverse events on drug development.

20. Management of Medical Emergencies*. Pre-trial interviews and screening procedures; up-to-date resuscitation procedures and guidelines; diagnosis and management of anaphylaxis and other severe allergic phenomena, cardiac arrhythmias, respiratory emergencies, syncope, convulsions and other neurotoxicity, dermatological adverse events; clinical pharmacology of drugs used in emergencies.

Quality

21. Quality of raw material and drug product. Identity of material, nature and quantity of impurities, stability, storage, certificates of analysis, role of the Qualified Person.

Regulatory, Ethical and Legal

22. Regulatory Requirements and Procedures for Phase I/II studies

23. Ethics Review. Principles of ethics review; ethical issues in non-therapeutic clinical research; guidelines for ethics committee composition and practice; principles of informed consent.

24. Indemnity and Negligence. Principles; types of indemnity; legal responsibilities; negligence, definition and avoidance.

25. Good Clinical Practice. Principles to ensure the validity of the data collected and the conclusions drawn; record keeping in clinical research; essential documents, responsibilities of the investigator, sponsor, monitor, regulatory authority, auditor; regulatory audit; fraud in clinical research.

26. Documentation. Summary of Data and Guidance for the Investigator section of Investigator's Brochure, protocols, clinical study reports, Clinical Trials Authorisation applications, Investigational Medicinal Product Dossiers.

Communication

27. Interpersonal Relationships. Effective negotiation with stakeholders, management of study personnel; team skills.

The above syllabus is common to the Diploma and Certificate in Human Pharmacology but trainees in the Certificate programme are not expected to have comprehensive knowledge of items marked *.