PharmaTrain Syllabus Revision Project
Review • Revise • Renew

Tables of changes to the PharmaTrain Syllabus

Introduction

The Faculty of Pharmaceutical Medicine ('the Faculty') coordinated the PharmaTrain syllabus revision project under the auspices of the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine (IFAPP), the PharmaTrain Federation and the Faculty. The purpose of the project was to review, revise and renew the PharmaTrain Syllabus 2010. The project started in March 2017 with the establishment of 14 syllabus section review teams, which were tasked with reviewing and proposing revisions to their sections of the syllabus. The teams' proposed revisions were submitted to the Project Coordination Group for agreement and reconciliation. The project was completed in December 2017 with the ratification of the updated syllabus – the PharmaTrain Syllabus 2018.

The tables in this document set out the sections and topics that have been revised or retained.

Professor Peter Stonier
Project Convenor, Faculty of Pharmaceutical Medicine
December 2017

Section Titles		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
Section 1 – Discovery of Medicines	Section 1 – Discovery of Medicines	
Section 2 – Development of Medicines: Planning	Section 2 – Development of Medicines: Planning	
Section 3 – Non-Clinical Testing	Section 3 – Non-Clinical Testing	
Section 4 – Pharmaceutical Development	Section 4 – Pharmaceutical Development	
Section 5 – Exploratory Development (Molecule to Proof-of-Concept)	Section 5 – Exploratory Development (Molecule to Proof of Concept)	Removed hyphens.
Section 6 – Confirmatory Development: Strategies	Section 6 – Confirmatory Development	“Strategies” deleted.
Section 7 – Clinical Trials	Section 7 – Clinical Trials	
Section 8 – Ethics and Legal Issues	Section 8 – Ethics and Legal Issues	
Section 9 – Data Management and Statistics	Section 9 – Data Management and Statistics	
Section 10 – Regulatory Affairs	Section 10 – Regulatory Affairs	
Section 11 – Drug Safety, Pharmacovigilance and Pharmacoepidemiology	Section 11 – Drug Safety, Pharmacovigilance and Pharmacoepidemiology	

Section Titles		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
Section 12 – Information, Promotion and Education	Section 12 – Information, Promotion and Education	
Section 13 – Economics of Healthcare	Section 13 – Economics of Healthcare, Health Economics and Pharmacoeconomics	Added “Health Economics and Pharmacoeconomics”.
Section 14 – Therapeutics		The whole of section 14 has been deleted. The topics in this section, that are relevant to pharmaceutical medicine, have been transferred to the appropriate sections of the 2018 syllabus.

Section Topics		
Section 1 – Discovery of Medicines		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
1.1 Strategy and organisation of research including collaborative approaches e.g. with academia	1.1 Strategy and organisation of research including collaborative approaches with academia and small- and medium-sized enterprises; in- and out-licensing, medical due diligence; intellectual property	Amended.
1.2 Disease models; target identification, validation and selection	1.2 Unmet medical need; target identification and validation	
1.3 Receptor-based approaches: agonists, antagonists, enzyme inhibitors, genomics, proteomics	1.3 Receptor-based approaches (agonists and antagonists), enzyme inhibitors; genomics, proteomics, metabolomics	
1.4 The principle steps in discovering, modifying, assessing and patenting new chemical and biological compounds		Deleted.
1.5 Other therapeutic approaches e.g. herbal and other natural products, drug-coupled devices and advanced therapies	1.4 Other therapeutic approaches: natural products, drug-coupled devices, advanced therapies e.g. gene therapy, cell therapies, tissue engineering	Amended and renumbered 1.4 in 2018 syllabus.
1.6 Lead optimisation and candidate compound selection for further development	1.5 Hit-to-lead, lead optimisation and candidate compound selection for further development	Amended and renumbered 1.5 in 2018 syllabus.
1.7 *In vitro* and *in vivo* testing of new compounds	1.6 *In silico*, *in vitro* and *in vivo* testing of new compounds	Amended and renumbered 1.6 in 2018 syllabus.

Section Topics		
Section 1 – Discovery of Medicines		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
1.8 Principles of translational medicine	1.7 Principles of translational medicine	Renumbered 1.7 in 2018 syllabus.
1.9 Relationship between animal and human pharmacology, molecular biology and physiology e.g. biomarkers, functional imaging, modeling and simulation	1.8 Relationship between animal and human pharmacology, molecular biology and physiology e.g. biomarkers, functional imaging, modeling and simulation	Renumbered 1.8 in 2018 syllabus.

Section Topics		
Section 2 – Development of Medicines: Planning		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
2.1 The elements and functions necessary in the integrated development of a new medicine at a corporate and international level	2.1 The elements and functions necessary in the integrated development of a new medicine at a corporate and international level	
2.2 Quality management	2.2 Quality management planning	Amended.
2.3 Project management techniques: drug development plan, project teams, tools and decision-making from target product profile (TPP) and target product claims (TPC) to registration dossier submission	2.3 Project management techniques: drug development plan, project teams, tools and decision-making from target product profile (TPP) and target product claims (TPC) to registration dossier submission and life-cycle management	Amended.
2.4 Programme planning in special cases e.g. women, elderly, paediatrics, orphan drugs	2.4 Programme-planning in special populations e.g. elderly, children, people with rare diseases, incapacitated people	Amended.
2.5 Programmes in developing countries	2.5 Programmes in developing countries	
2.6 R&D portfolio planning including in- and out-licensing of medicines (business development)	2.6 R&D portfolio planning including in- and out-licensing of medicines (business development)	
2.7 Resource planning: budgeting and cost control	2.7 Resource planning: budgeting and cost control	

Section Topics		
Section 2 – Development of Medicines: Planning		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
	2.8 Corporate finance relevant to medicines development: financial control, return on investment, fixed assets, budgeting, accounting, profitability	New topic.

Section Topics		
Section 3 – Non-Clinical Testing		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
3.1 Pathophysiology- and molecular biology-based pharmacology	3.1 Use of *in silico*, animal- and cell-based models of disease mechanisms to study the pharmacology of a new drug	Amended.
3.2 Differences in non-clinical safety and toxicity packages between small molecules and biological	3.2 Differences in non-clinical safety and toxicity packages between small molecules, biological medicines, advanced therapies	Amended.
3.3 The fundamental differences and similarities between the pharmacology and toxicology of compounds and their metabolites in animals and man, and their qualitative and quantitative assessment	3.3 The differences and similarities between the pharmacology and toxicology of compounds and their metabolites in animals, humans and cell preparations that provide qualitative and quantitative assessment through: genotoxicity, general toxicity, toxicokinetics, pharmacokinetics, drug metabolism, safety pharmacology, immunotoxicity, reproductive toxicity, carcinogenicity; duration of studies to support clinical trials and marketing approval	Amended.
3.4 The purpose of descriptive and quantitative *in vitro* and *in vivo* testing	3.4 The purpose of descriptive and quantitative *in silico, in vitro* and *in vivo* toxicity testing; the choice of appropriate tests for acute and chronic drug administration	Amended.

Section Topics		
Section 3 – Non-Clinical Testing		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
3.5 The choice of and the predictive value of these tests for acute, chronic, reproductive, genetic and immune toxicology, and carcinogenicity		Deleted.
3.6 Common mechanisms of damage to organs and their detection or elucidation	3.5 The common mechanisms of drug-induced organ damage and dysfunction; detection and elucidation; pathological assessment e.g. structural staining and immune-histochemistry; functional assessment e.g. QTc interval testing, liver and lung function tests	Amended and renumbered in 2018 syllabus.
3.7 The scheduling of toxicology tests linked to development plans, to regulatory needs, to human and animal pharmacology, and to intended clinical use and route(s) of administration	3.6 The scheduling of toxicity tests linked to product development plans, regulatory needs, human and animal pharmacology, intended clinical use and route(s) of administration	Amended and renumbered in 2018 syllabus.
3.8 The size, cost and administration of the toxicology programme, its data management, quality assurance and report writing	3.7 The size, cost and administration of the toxicology programme, its data management, quality assurance and reporting	Renumbered in 2018 syllabus.

Section Topics		
Section 3 – Non-Clinical Testing		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
3.9 The regular review of toxicology, its inclusion into clinical trial protocols and investigator brochures, and the appropriate planning and correlation with the clinical evaluation of potential and observed toxicity in patients	3.8 The regular review of toxicity, its inclusion into clinical trial protocols and investigator brochures, and the appropriate planning and correlation with the clinical evaluation of potential and observed toxicity in patients	Renumbered in 2018 syllabus.
3.10 Safety pharmacology; hypersensitivity	3.9 Safety pharmacology including drug hypersensitivity of both small and large molecules	Amended and renumbered in 2018 syllabus.
3.11 Toxicokinetics; *in vitro* and *in vivo* study of metabolism; ADME	3.10 Toxicokinetics; *in vitro* and *in vivo* study of metabolism; administration, distribution, metabolism, elimination (ADME)	Amended and renumbered in 2018 syllabus.
	3.11 The non-clinical study of biological medicines, vaccines, advanced therapies e.g. gene therapy, cell therapies, tissue engineering	New topic.
	3.12 The non-clinical study of biopharmaceutical formulations	New topic.

Section Topics		
Section 4 – Pharmaceutical Development		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
4.1 Pharmaceutical development of drug substance and drug product: formulations; manufacture and supply of materials; labelling and presentation; stability and storage; purity; compatibility; disposal, including biotechnology products	4.1 Pharmaceutical development of drug substance and drug product, including biological medicines and advanced therapies: formulations; manufacture and supply of materials; labelling and presentation; stability and storage; purity; compatibility; disposal	Amended.
4.2 The economic primary production of new compounds and secondary production of research and market formulations	4.2 The economic primary production of new compounds and secondary production of research and market formulations	
4.3 The choice of formulations depending upon the characteristics of the compound and the intended uses of the product	4.3 The choice of formulations depending upon the characteristics of the compound and the intended uses of the product	
4.4 The principles of testing formulations for bioequivalence, stability, impurity and incompatibility leading to a final specification, including the development of biosimilar formulations	4.4 The principles of *in vitro* and *in vivo* testing of formulations for bioequivalence, stability, impurity and incompatibility leading to a final specification, including formulations of follow-on drugs - generics, biosimilars	Amended.
4.5 The concept of blinding: preparing matching placebo and competitor products	4.5 Planning clinical trial supply requirements; packaging and labelling of clinical trial supplies; stability and storage requirements; supply distribution; disposal of remaining stocks	Order of topics 4.5 and 4.6 in 2010 syllabus changed in 2018 syllabus. No amendments made to 2010 4.6 topic.

Section Topics		
Section 4 – Pharmaceutical Development		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
4.6 Planning clinical trials supply requirements; packaging and labelling of clinical trial supplies (including stability and storage requirements); distributing supplies and disposing of remaining stocks	4.6 Clinical trial supplies: preparing matching placebo and competitor products	Order of topics 4.5 and 4.6 in 2010 syllabus changed in 2018 syllabus. Amendment made to 2010 4.5 topic.
	4.7 Pharmacopoeias: role, use and hierarchy	New topic. Amended 10.20 in 2010 syllabus moved to section 4.

Section Topics		
Section 5 – Exploratory Development (Molecule to Proof of Concept)		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
5.1 Intended therapeutic indications, biomarkers, efficacy end-points and criteria for 'go', 'no-go' decisions	5.1 Intended therapeutic indications, biomarkers for target engagement, efficacy and safety requirements, efficacy and safety end-points and criteria for 'go' / 'no-go' decisions for entry into humans and progression to Proof of Concept trials	Amended.
5.2 Assessment of non-clinical data and risk as prerequisites before administration to man	5.2 Assessment of non-clinical data and the risk of hazards as prerequisites before administration to humans	Amended.
5.3 Exploratory phase 0 trials	5.3 Phase 0 studies: exploratory microdose and sub-therapeutic dose studies; the importance, limitations and uses of microdoses (ICH M3)	Amended.
5.4 The early clinical development plan: the objectives, design, conduct and analysis of early exploratory development studies; modelling and simulation; tolerability, metabolism, pharmacokinetics, pharmacodynamics and safety in man; problems of participant's safety in the concept of blinding	5.4 The early clinical development plan: exploratory development studies: - from First in Human to Proof of Concept - modelling and simulation - tolerability, metabolism, pharmacokinetics, pharmacodynamics, safety in humans - safety assessment in patient and healthy volunteer populations - dose escalating safety committees (membership and role) - special considerations for advanced therapies and drug-coupled devices	Amended.

Section Topics		
Section 5 – Exploratory Development (Molecule to Proof of Concept)		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
5.5 Pharmacokinetics, ADME and pharmacokinetic / pharmacodynamic models	5.5 Pharmacokinetics, ADME, pharmacokinetic / pharmacodynamic models, including concepts of half-life, volume of distribution, clearance; intrinsic and extrinsic factors which affect the pharmacokinetics of an innovative medicinal product; dosage and accumulation, bioavailability, bioequivalence and population pharmacokinetics	Amended.
5.6 Concepts of half-life, volume of distribution, clearance		Deleted
5.7 Bioavailability and bioequivalence		Deleted
5.8 Extrinsic and intrinsic factors		Deleted
5.9 Population pharmacokinetics		Deleted
5.10 Pharmacogenetics / pharmacogenomics	5.6 Pharmacogenetics / pharmacogenomics	Renumbered in 2018 syllabus.
5.11 Applicability of pharmacokinetics to dosage regimen and study design	5.7 Starting dose and dose escalation plan for First in Human and early clinical studies, including applicability of pharmacokinetics to dosage regimen and study design in First in Human studies and subsequent Phase II and Phase III clinical trials	Amended and renumbered in 2018 syllabus.

Section Topics		
Section 5 – Exploratory Development (Molecule to Proof of Concept)		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
5.12 First administration to patients: principles of proof-of-concept and dose-finding studies	5.8 First in Human studies: patients and healthy volunteers; principles of Proof of Concept and dose-finding studies; biomarker qualification / validation for Proof of Concept studies	Amended and renumbered in 2018 syllabus.
5.13 Impact of results on planned therapeutic indications, on predicted dosage schedule, on additionally required animal toxicology and on drug delivery concepts / forms	5.9 Impact of results on planned therapeutic indications, predicted dosage schedules and drug delivery concepts / formulations; additional animal toxicology requirements; reformulation studies; new pharmacology studies; risk prediction algorithms to assess safety risks and enable development of risk management approaches to be applied during continued development	Amended and renumbered in 2018 syllabus.

Section Topics		
Section 6 – Confirmatory Development		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
	6.1 Options for the clinical development plan (CDP); asset risk assessment and mitigation; schedules and decision points for the confirmatory clinical development programme	Amended 2010 6.4 topic reordered in 2018 syllabus.
6.1 Final definition of therapeutic indications, categories of patients, delivery system(s), dosage forms and dosage regimens	6.2 Translation of the defined target product profile (TPP) into the confirmatory clinical development programme design; pivotal and other Phase III studies; selection of primary and secondary endpoints and comparators for Phase III clinical trials; final definition of therapeutic indications; risk minimisation measures for research participants	Amended 2010 6.1 topic; split in two topics (see 2018 6.3 topic); reordered in 2018 syllabus.
6.2 Planning and global coordination / harmonisation of pre-licensing and post-licensing clinical trial programmes; use of non-clinical and existing clinical trial data		See 2018 6.4 below.
6.3 Estimated treatment population; clinical trial supplies and costs up to registration		Deleted.

Section Topics		
Section 6 – Confirmatory Development		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
	6.3 Choice of countries / regions to participate in confirmatory clinical trials; patient numbers and selection criteria; delivery systems; dosage forms; dosage regimens; clinical trial supplies - ensuring all these are appropriate for this stage of development	New topic derived from amended 2010 6.1 topic.
6.4 Decision points, schedules and resources required for a confirmatory clinical development plan (CDP)	See 2018 6.1 topic above.	
	6.4 Planning and global coordination including alignment of pre-licensing and post-licensing clinical trial programmes; permitted use of competitor class data, non-clinical data and existing clinical trial data	Amended 2010 6.2 topic; renumbered in 2018 syllabus.
6.5 Life-cycle management planning: extension of therapeutic claims, new formulations, new dosage schedules by peri-marketing trials, post-marketing (surveillance) studies and quality of life measures	6.5 Life-cycle management planning: label extension of therapeutic claims and new formulations	Amended.

Section Topics		
Section 6 – Confirmatory Development		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
6.6 Regulatory review of existing and emerging research results	6.6 Obtaining and implementing feedback from regulatory agencies and / or health technology assessment bodies on emerging research results and development plans through scientific advice procedures; consulting with other external bodies on proposed development plans	Amended.

Section Topics		
Section 7 – Clinical Trials		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
7.1 Choice of trial design, of placebo and of other comparators, of patient populations, of sample size, of locations, of randomisation, of end-points and of statistical analysis	7.1 Choice of trial design, considering: non-inferiority / superiority / other design; placebo / other comparators; patient populations; sample size; locations; randomisation; end-points; statistical analysis	Amended.
7.2 New trial designs e.g. adaptive design	7.2 New trial designs and required technologies	Amended.
7.3 Non-interventional / observational study design	7.3 Post-authorisation clinical development: Phase IV clinical trials; non-interventional / observational studies; Real World Evidence (RWE) generation; post-authorisation studies; patient group registries	Amended.
7.4 Principles of Good Clinical Practice and procedures applied in all stages of the clinical trial process to ensure subject protection, scientific validity and safety		Deleted.
7.5 Investigator Brochure: content, review and maintenance	7.4 Investigator Brochure: content, review and maintenance	Renumbered in 2018 syllabus.
7.6 Protocol preparation and review	7.5 Protocol development and amendments	Amended and renumbered in 2018 syllabus.
7.7 Feasibility and investigator recruitment	7.6 Clinical trial feasibility and investigator recruitment; pre-study visits; investigator meetings and investigator training	Amended and renumbered in 2018 syllabus.

Section 7 – Clinical Trials		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
7.8 Pre-study visits and investigator meetings; investigator training		Deleted.
7.9 Project management including resources; vendors and budget	7.7 Trial management including investigational site management and site qualification assessment	Amended and renumbered in 2018 syllabus.
7.10 Contractual arrangements with investigators and contract research organisations, including publication rights	7.8 Contractual arrangements with investigators, academic institutions / hospitals, contract research organisations, site management organisations; publication rights	Amended and renumbered in 2018 syllabus.
7.11 Clinical trial registries	7.9 Clinical trial registries	Renumbered in 2018 syllabus.
7.12 Investigative site management		Deleted.
7.13 Within-trial decisions e.g. code-breaking, interim analysis, premature termination	7.10 Within-trial decisions e.g. code-breaking, interim analysis, data and safety monitoring committee (DSMC), premature termination	Amended and renumbered in 2018 syllabus.
7.14 Study medication handling and drug accountability	7.11 Study medication handling and drug accountability	Renumbered in 2018 syllabus.
7.15 Adverse event assessment and reporting; emergency coverage	7.12 Adverse event assessment and reporting; emergency cover	Amended and renumbered in 2018 syllabus.
7.16 Monitoring and source document verification	7.13 Monitoring and source document verification; evolution of clinical trial monitoring	Amended and renumbered in 2018 syllabus.

Section 7 – Clinical Trials		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
7.17 Trial master file (TMF)	7.14 Trial master file (TMF)	Renumbered in 2018 syllabus.
7.18 Quality management system; SOPs; quality assurance and quality control; independent audits; inspections	7.15 Quality management system; quality manual; standard operating procedures; quality assurance and quality control; independent audits; inspections	Amended and renumbered in 2018 syllabus.
7.19 Clinical trial report	7.16 Reporting of clinical trial data: data sharing and open data, transparency, aggregate clinical trial report reviews, annual clinical trial reports	Amended and renumbered in 2018 syllabus.
	7.17 Consideration for special populations in clinical trials e.g. elderly, children, extreme ages e.g. prematures-neonates, incapacitated people; clinical trials in rare diseases	New topic.
	7.18 Medical device and drug-coupled device trials	New topic.

Section 8 – Ethics and Legal Issues		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
8.1 Ethical issues in biomedical research and pharmaceutical medicine		See comment below.
8.2 Ethics: principles, history including Declaration of Helsinki, Directive 2001/20/EC, ethical review, informed consent, safety and human dignity of research subjects		See comment below.
	8.1 Ethics: principles, history including Declaration of Helsinki, Directive 2001/20/EC, ethical review, informed consent, safety and human dignity of research participants, role of ICH GCP and other Good Practices (GxPs)	Amended 2010 8.2 topic; renumbered in 2018 syllabus.
	8.2 Ethical issues in biomedical research and pharmaceutical medicine	Renumbered in 2018 syllabus.
8.3 Protection of research subjects, minimising risk including site qualification assessment	8.3 Protection of research participants; sponsor and investigator responsibilities, in particular, to avoid conflicts of interest	Amended.
8.4 Ethical aspects in research questions and study designs for first-in-human to post marketing and epidemiological studies, including placebo and comparator choice	8.4 Ethical aspects in research questions and study designs for First in Human to post-marketing and epidemiological studies, including scientific rationale, statistical robustness, appropriate patient populations, comparators and choice of endpoints; ensuring equipoise in comparator clinical studies; consideration of conflicts of interest	Amended.
8.5 Conflict of interest and equipoise		Deleted.

Section 8 – Ethics and Legal Issues		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
8.6 Ethical aspects of subject contact and recruitment	8.5 Ethical aspects of methods of recruitment including database searches and advertising; participant contact; participant reimbursement	Amended and renumbered in 2018 syllabus.
8.7 Ethical issues of reimbursement, compensation and inducement		Deleted.
8.8 Risks, benefits and burden of study participation		Deleted.
8.9 The informed consent process	8.6 Informed consent process, including defining benefit-risk balance, requirements for study participation including for special populations e.g. elderly, children, emergency research, incapacitated people	Amended and renumbered in 2018 syllabus.
8.10 Privacy, confidentiality and data protection	8.7 Privacy, confidentiality, international standards for data protection and consensual dissemination of clinical trial data	Amended and renumbered in 2018 syllabus.
8.11 Indemnity and insurance for participants, investigators, institutions; complaint procedures	8.8 Indemnity and insurance for participants, investigators and institutions; complaint procedures	Amended and renumbered in 2018 syllabus.
8.12 Ethical aspects of study follow-on	8.9 Ethical aspects of clinical trial follow-on: continuation of study medication to study participants, pre-marketing authorisation, availability pre-reimbursement	Amended and renumbered in 2018 syllabus.

Section 8 – Ethics and Legal Issues		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
8.13 Ethical aspects of taking trial samples for genomic and related analyses	8.10 Ethical aspects of trial samples for genomic and related analyses: scientific rationale, ethics and consequences of anonymisation; biobanks	Amended and renumbered in 2018 syllabus.
8.14 Ethical aspects of clinical trials in vulnerable populations	8.11 Ethical aspects of clinical trials in special populations e.g. elderly, children, emergency research, incapacitated people	Amended and renumbered in 2018 syllabus.
8.15 Ethical aspects of advanced therapy medicinal products	8.12 Ethical aspects of all stakeholders involved in research of advanced therapies e.g. gene therapy, cell therapies, tissue engineering	Amended and renumbered in 2018 syllabus.
8.16 Ethical aspects of clinical trials in third world and emerging countries	8.13 Ethical aspects of clinical trials in developing countries	Amended and renumbered in 2018 syllabus.
8.17 Fraud and misconduct in biomedical research and clinical development	8.14 Fraud and misconduct in biomedical research and clinical development	Renumbered in 2018 syllabus.

Section 9 – Data Management and Statistics		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
9.1 Options for data collection (manual and electronic) and standardisation 9.2 Case report form (CRF) design and review 9.3 Creation, maintenance and security of databases, software validation and archiving 9.4 From source document to CRF completion, CRF review and corrections, data entry, query generation and resolution, coding of adverse events, database lock 9.5 The purpose and fundamentals of statistics 9.6 Role and responsibilities of the statistician 9.7 The statistical analysis plan 9.8 Trial design: pre-trial decisions and specifications; risk factors; confounding variables 9.9 Hypothesis testing: the null hypothesis, Type I and Type II error, significance, power 9.10 Sample size calculation	**Statistical Aspects of Study Design** 9.1 Fundamentals: randomisation, choice of endpoints, avoidance of bias, avoidance of missing data, sample size calculation 9.2 Interim analyses: efficacy, futility, harm 9.3 The design of dose-finding studies 9.4 Equivalence and non-inferiority trials: rationale, choice of margin 9.5 Adaptive designs: basic ideas including advantages, concerns, avoidance of statistical and operational bias **Data Management** 9.6 Data collection: options, to include manual and electronic, including diaries 9.7 Case report form (CRF) design and completion; source data verification, query generation and resolution	Topics retained or amended; new topics added; and all topics renumbered in 2018 syllabus.

Section 9 – Data Management and Statistics		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
9.11 Minimising bias 9.12 Types of data and standardisation of measurement 9.13 Patient-reported outcomes e.g. diaries; quality of life measures 9.14 Statistical analysis of efficacy end-points and of safety 9.15 Interim analysis 9.16 Paired and non-paired tests, parametric and non-parametric tests, confidence limits 9.17 Handling of rating and visual analogue scales, patient diaries and laboratory values 9.18 Handling of missing data 9.19 Sensitivity and specificity of tests	9.8 Data processing: data entry, coding of adverse events, medical history and concomitant medications; identification of protocol violations and deviations 9.9 Databases: maintenance, security, standardisation, streamlining the processes; Clinical Data Interchange Standards Consortium (CDISC) **Statistical Methods for Analysis** 9.10 Fundamentals: Null and alternative hypotheses, type I and type II errors, p-values, confidence intervals, power, analysis sets 9.11 Endpoints: endpoint types (continuous, binary / categorical, time-to-event, rating scales), data transformation, primary and secondary endpoints, dealing with multiplicity, evaluating equivalence and non-inferiority 9.12 Specific methodologies: simple statistical tests (parametric and non-parametric), Odds Ratios, Risk Ratios, Hazard Ratios, Kaplan-Meier curves, modelling to correct for baseline imbalances and to reduce variation 9.13 Evaluating homogeneity: Forest plots and subgroup evaluation, testing for interaction	Topics retained or amended; new topics added; and all topics renumbered in 2018 syllabus.

Section 9 – Data Management and Statistics		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
9.20 True and apparent incidence and prevalence 9.21 Interpretation of analyses; assessment of violations, withdrawals, errors, bias 9.22 Statistical principles and issues in statistical report writing: data manipulation, transformation and merging; preparation of the statistical report 9.23 Clinical interpretation of trial results 9.24 Dealing with confounding factors and bias 9.25 Critical review of publications	9.14 Dealing with missing data through imputation 9.15 Bayesian statistics; basic ideas 9.16 Safety data: tables and graphs for the evaluation of adverse events, laboratory data and other data relating to safety 9.17 Diagnosis: sensitivity, specificity and introduction to Receiver Operating Characteristic (ROC) curves 9.18 Meta-analysis: distinction versus pooling, fixed and random effects models 9.19 Observational studies: matching to minimise bias **The Statistics Process** 9.20 Content for the protocol statistical methods section and the Statistical Analysis Plan 9.21 Writing the Statistical Study Report and contributing to the Clinical Study Report and clinical publications; to include the clinical interpretation of statistical analyses 9.22 Critical review of publications	Topics retained or amended; new topics added; and all topics renumbered in 2018 syllabus.

Section 10 – Regulatory Affairs		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
10.1 Background to and general principles of medicines regulation	10.1 Background to and general principles of medicines regulation; evolution of control mechanisms; differences between agencies	Amended.
10.2 Philosophy of regulatory oversight; practical input of international bodies e.g. WHO, WMA, CIOMS and national agencies	10.2 Philosophy of regulatory oversight; practical input of international bodies e.g. World Health Organisation (WHO), World Medical Association (WMA), Council for International Organisations of Medical Sciences (CIOMS), and national agencies	Amended.
10.3 The evolution of control mechanisms; differences between agencies		Deleted; contained in 2018 topic 10.1.
10.4 Activities and contribution of International Conference on Harmonisation (ICH)	10.3 Activities and contribution of International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)	Amended and renumbered in 2018 syllabus.
10.5 Good Manufacturing Practices; Good Laboratory Practices; Good Clinical Practices	10.4 Good Practices relevant to medicines development e.g. Good Manufacturing Practice, Good Laboratory Practice, Good Clinical Practice, Good Clinical Laboratory Practice, Good Pharmacovigilance Practice	Amended and renumbered in 2018 syllabus.
10.6 Integration of regulatory affairs into pre- and post-marketing; planning and review of product strategy	10.5 Integration of regulatory affairs into pre- and post-marketing; planning and review of product strategy	Renumbered in 2018 syllabus.

Section 10 – Regulatory Affairs		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
10.7 The approval, appeals and referrals processes in Europe; aspects of confidentiality, transparency and updating; maintaining Marketing Authorisations	10.6 Regulatory processes in Europe for the evaluation and approval of new medicinal products; scientific advice; appeal and arbitration procedures; procedures for maintaining, varying and cancelling European Marketing Authorisations; referrals processes; confidentiality and transparency	Amended and renumbered in 2018 syllabus.
10.8 Orphan drugs, paediatrics, advanced therapies, generics and biosimilars	10.7 Regulatory processes: rare diseases, children, advanced therapies	Amended and renumbered in 2018 syllabus.
	10.8 Regulatory processes: generics and biosimilars	New topic.
10.9 Regulatory management systems in Europe, US, Japan, ROW and local special regulatory requirements	10.9 Comparison of international regulatory systems: Europe, US, Japan, and the Rest of the World; local special regulatory requirements	Amended.
10.10 Clinical Trials regulations; EU Directives and Guidances and their diversity in national implementation, CTA including IMPD substantial amendments. Clinical trial regulations in other regions e.g. the US IND process	10.10 European regulations and guidance for Clinical Trial Application (CTA), maintenance and completion; EU single submission portal; substantial protocol modifications; transparency; clinical trial regulations in Europe, US, Japan and the Rest of the World	Amended.
10.11 Common Technical Document (CTD and eCTD); Overviews	10.11 Common Technical Document (CTD and eCTD); Clinical Overviews; Clinical Summaries	Amended.

Section 10 – Regulatory Affairs		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
10.12 Aggregate clinical trial report reviews, including annual reports and Common Technical Document (CTD) summaries		Deleted.
10.13 The preparation and submission of marketing applications in major countries (MAA, NDA, JNDA, CNDA)	10.12 The preparation and submission of marketing applications in major countries e.g. Marketing Authorisation Application (MAA), New Drug Application (NDA), Japanese NDA, Canadian NDA	Amended and renumbered in 2018 syllabus.
10.14 Product Information regulation: Summary of Product Characteristics; Package Insert; Patient Information Leaflets; Prescribing Information	10.13 Product Information regulation: Summary of Product Characteristics; Package Insert; Patient Information Leaflets	Amended and renumbered in 2018 syllabus.
10.15 Advertising and promotion regulation: promotional material		Deleted.
10.16 Prescription-only and over-the-counter medicines; switches	10.14 Prescription-only and over-the-counter medicines; switches	Renumbered in 2018 syllabus.
10.17 Provisions for and use of unlicensed medicines	10.15 Regulatory provisions for the use of unlicensed medicines	Amended and renumbered in 2018 syllabus.
10.18 Product defects and recall	10.16 Product restriction, suspension and withdrawal procedures; product defects and recall	Amended and renumbered in 2018 syllabus.
10.19 Medical device regulations	10.17 Medical device regulations	Renumbered in 2018 syllabus.

Section 10 – Regulatory Affairs		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
10.20 Pharmacopoeias		Deleted.
	10.18 Regulation of natural products e.g. herbals, synbiotics, traditional remedies, Chinese medicines	New topic.
10.21 Risk management: Risk Management Plans (RMPs) in the EU; Risk Evaluation and Mitigation Strategies (REMS) in the USA	10.19 Risk management: Risk Management Plan (EU); Risk Evaluation and Mitigation Strategies (USA); additional monitoring of authorised medicines e.g. inverted black triangle (EU), black box warning (USA)	Amended and renumbered in 2018 syllabus.
10.22 Safety Specification	10.20 Periodic Benefit Risk Evaluation Report (PBRER); Periodic Safety Update Report (PSUR); Development Safety Update Report (DSUR)	Amended and renumbered in 2018 syllabus.
10.23 Direct Healthcare Professional Communication		Deleted; covered in 2018 topic 12.2.
10.24 Product withdrawal procedures		Deleted.
10.25 Drug abuse and dependence		Deleted.
10.26 Off-label use and misuse		Deleted.
	10.21 Regulation and procedures for early access to medicines	New topic.
	10.22 Falsified and counterfeit medicines	New topic.

Section 10 – Regulatory Affairs		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
	10.23 Post-authorisation safety studies; post-authorisation efficacy studies; investigator-initiated studies	New topic.

Section 11 – Drug safety, Pharmacovigilance and Pharmacoepidemiology		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
11.1 The role of the pharmaceutical professional in drug safety and pharmacovigilance	11.1 The role of the pharmaceutical professional in drug safety and pharmacovigilance	
11.2 Assessment and classification of adverse events (AEs), adverse drug reactions (ADRs), Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARs); evidence for association and causality	11.2 Assessment and classification of Adverse Events, Adverse Drug Reactions, Serious Adverse Events and Suspected Unexpected Serious Adverse Reactions (SUSARs); evidence for association and causality	
11.3 The concept of benefit / risk assessment, determination of causal relationship between the medicinal product and the adverse event	11.3 The concept of benefit-risk balance assessment	Amended.
11.4 Collection of adverse events in clinical trials	11.4 Collection of adverse events in clinical trials	
11.5 Role of sponsors and investigators in reporting; regulatory requirements	11.5 The role of investigators, clinicians, study monitors, sponsors and manufacturers in the pre- and post-marketing phases to detect, assess and report adverse events and suspected adverse drug reactions; regulatory reporting requirements in the pre- and post-marketing phases; medical literature reports	Amended.
11.6 Predisposing factors in health and disease	11.6 Predisposing factors and the impact of pre-existing disease on the susceptibility for and severity of adverse events and how to minimise risk	Amended.

Section 11 – Drug safety, Pharmacovigilance and Pharmacoepidemiology		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
11.7 Spontaneous reporting post-marketing	11.7 Post-marketing spontaneous reporting	Amended.
11.8 Dosage, accumulation, medication errors and interactions	11.8 Reportable events: overdose, medication errors, off-label use, misuse and abuse, experience during pregnancy	Amended.
11.9 Drug adherence / compliance		Deleted.
	11.9 Drug interactions	New topic.
11.10 Periodic Safety Update Reports		Deleted; covered in 2018 10.19 and 10.20 topics.
11.11 Pharmacoepidemiology	11.10 Pharmacoepidemiology	Renumbered in 2018 syllabus.
11.12 Main sources of epidemiological pharmacovigilance information	11.11 Main sources of epidemiological pharmacovigilance information	Renumbered in 2018 syllabus.
11.13 Signal detection, interpretation and management	11.12 Signal detection, interpretation and management	Renumbered in 2018 syllabus.
11.14 Post-authorisation safety studies		Deleted; covered in 2018 10.23 topic.
11.15 Post-authorisation risk management including issue and crisis management	11.13 Post-authorisation risk management including issue and crisis management	Renumbered in 2018 syllabus.
11.16 Risk communication	11.14 Risk communication	Renumbered in 2018 syllabus.

Section 12 – Information, Promotion and Education		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
12.1 Information to patients and patient organisations, prescribing and compliance	12.1 Information and disclosure to patients and patient organizations; compliance in patient engagement activities	Amended.
12.2 Product Information content and preparation: Summary of Product Characteristics; Package Insert; Patient Information Leaflets; Prescribing Information		Deleted.
12.3 Product support and promotion	12.2 Non-promotional product support, medical information, direct healthcare professional communication (DHPC) and other non-promotional activities; pre-licence activities	Amended and renumbered in 2018 syllabus.
12.4 Codes of conduct: promotional policy and procedures; Good Promotional Practice	12.3 Codes of conduct: promotional policy and procedures; Good Promotional Practice; pre-approval and post-approval activities; disclosure of transfers of value	Amended and renumbered in 2018 syllabus.
12.5 Advertising: claims, ethics, control and approval	12.4 Advertising: claims, prescribing information, media and digital methods, audiences, compliance, ethics, control and approval	Amended and renumbered in 2018 syllabus.
12.6 Publication strategy	12.5 Publication strategy for clinical trials and clinical research studies	Amended and renumbered in 2018 syllabus.
12.7 Sales representative training: material and aids		Deleted.
	12.6 Support of the development of clinical guidelines	New topic.

Section 12 – Information, Promotion and Education		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
	12.7 Post-marketing studies	New topic.
12.8 Educational meetings; sponsored meetings and sponsored publications	12.8 Educational meetings; sponsored meetings and sponsored publications	
	12.9 Characterising patient preferences used in health technology assessment dossiers or research e.g. discrete choice experiments (DCE), focus groups	New topic.
	12.10 Principles and practice of marketing; market structure and competition; market analysis	New topic; derived from items from 2010 topic 13.5.

Section 13 – Economics of Healthcare, Health Economics and Pharmacoeconomics		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
13.1 Principles of healthcare economics; principles of justice and equity in healthcare economics	13.1 Principles and methods of the economics of healthcare, health economics and pharmacoeconomics	Amended.
13.2 Principles of pharmacoeconomics		Deleted; included in 2018 13.1 topic.
13.3 Evidence Based Medicine; outcomes research	13.2 Evidence-based medicine (EBM)	Amended and renumbered in 2018 syllabus.
13.4 Quality of Life, concept and measurement instruments	13.3 Health-related quality of life / patient-reported outcomes: concepts and methods of measurement.	Amended and renumbered in 2018 syllabus.
13.5 Principles and practice of marketing; market structure and competition; market analysis, pricing and reimbursement strategies; national and local formularies	13.4 Pricing and reimbursement strategies e.g. value-based pricing, reference pricing, risk-sharing schemes, advance budgetary notifications	Amended and renumbered in 2018 syllabus.
13.6 Medical marketing and market access	13.5 Market access, national and local formularies	Amended and renumbered in 2018 syllabus.
13.7 Measurement of healthcare efficiency, governmental policy and third party reimbursement	13.6 Measurement of healthcare efficiency: principles of international governmental policy and third-party reimbursement	Amended and renumbered in 2018 syllabus.
13.8 Economics of industry: competition, licensing, co-marketing	13.7 Economics of industry: competition, licensing, co-marketing and life-cycle management to include generics, biosimilars, parallel imports and switching strategies	Amended and renumbered in 2018 syllabus.

Section 13 – Economics of Healthcare, Health Economics and Pharmacoeconomics		
PharmaTrain Syllabus 2010	**PharmaTrain Syllabus 2018**	**Comment**
13.9 Financial control, return on investment, fixed assets, budgeting, accounting, profitability		Deleted; included in 2018 2.8 topic.
13.10 Generics and biosimilars, parallel imports, OTC; switching strategies		Deleted; incorporated in 2018 13.7 topic.
13.11 Health Technology Assessment (HTA) including meta-analysis and systematic review; health economics evaluation studies	13.8 The appraisal of health-economic evidence, systematic reviews and meta-analyses, health technology assessment	Amended and renumbered in 2018 syllabus.
	13.9 Patient access to medicines: alternative funding routes for non-reimbursed products; preparing a simple economic impact model	New topic.