

Unit 1: Drug Development Process and Ethics in Biomedical Research

Free notes at pharmacolearn.fyi

Clinical Research, subject code MPP104T, is the fourth core theory subject of M.Pharm Pharmacy Practice, Semester 1. It carries 4 credits and 60 hours of theory, taught at 4 hours per week, for 100 marks, and its five units are of equal length at 12 hours each in the PCI scheme. Its scope, as the syllabus states it, is to give students the opportunity to learn the drug development process, especially the phases of clinical trials and the ethical issues involved in the conduct of clinical research,. In India, clinical trials and bioavailability and bioequivalence studies of new drugs and investigational new drugs now run under the New Drugs and Clinical Trials Rules, 2019. No approval timelines, compensation formulas, sample size figures or institutional procedures are stated, because they are set by rule, amendment and institution and the syllabus prints none.

1.1 Introduction: what clinical research is and why medicines need it

Clinical research is the systematic study of health and disease in human beings, carried out to produce knowledge that can be generalised: whether a treatment works, how safe it is, how it behaves in the body, and how its benefits and harms compare with the alternatives. Only structured human study can do that. Clinical research is therefore not a regulatory hurdle placed after the real science: it is the stage at which a candidate medicine becomes, or fails to become, a medicine at all, and every later unit of this subject exists to protect the two things that make its results believable: the rights and safety of the participants, and the credibility of the data.

1.2 The drug development process: the whole road in outline

The drug development process carries an idea for a treatment to an approved product and beyond. It begins in discovery, where a disease process is understood well enough to choose a target and compounds are found or made that act on it, and continues in preclinical development, where candidates are tested in laboratory systems and animals for activity, for how the body handles them, and for toxicity, and where the formulation a trial can use is worked out. Most candidates end here, and they are meant to: each early stage exists to stop weak candidates cheaply and safely before any human being is exposed. The survivors cross into clinical development through the investigational application of Section 1.5 and are studied in the phases of Unit 2, then a successful programme is assembled into a marketing application and reviewed on the total evidence of quality, safety and efficacy. Approval is not the end of learning: post marketing study and surveillance, the Phase IV world of Unit 2, continue the safety picture for as long as the product is used.

The drug development road, stage by stage

Discovery: target chosen, compounds found or made,
activity shown in laboratory systems



Preclinical development: pharmacology, how the body
handles the compound, toxicity, formulation for trials



Investigational application: the evidence assembled
and permission sought to test in humans

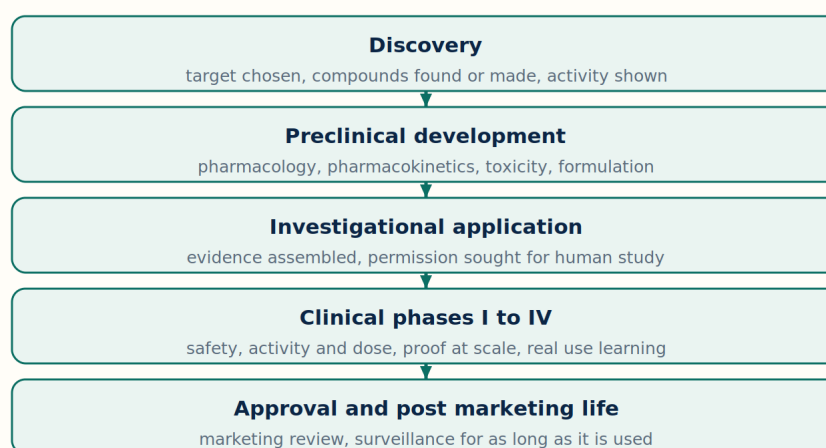


Clinical phases: safety and handling, dose and early
effect, proof at scale, learning after approval



Marketing review, approval, and continuing
post marketing study and safety surveillance

The drug development process



A funnel: numbers fall, cost and human exposure rise, at every stage

© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: The development funnel. Each stage exists to stop weak candidates before the next, more costly and more human, stage begins.

1.3 Various approaches to drug discovery

The syllabus names various approaches to drug discovery, and an examination answer should present them as complementary routes to the same starting point: a compound, or a small set of compounds, with a credible action on a chosen target and a profile worth developing. The classical pharmacological approach screens substances for a desired effect in test systems and animal models, observing the effect first; the rational, target based approach selects and validates a molecular target and designs or screens compounds against it, at modern scale in automated high throughput systems; chemical approaches modify a known active structure to improve potency, selectivity, handling or safety, the lead optimization of medicinal chemistry. Biological approaches produce the medicine as a biological product, antibodies and other proteins made in living systems. However a lead is found, the same questions decide whether it proceeds: does it act potently and selectively on the intended target, can it reach that target in the body, does it survive long enough to act, and does its early safety profile leave room for a usable dose.

1.4 Preclinical development: the bridge to human study

Between discovery and the first human dose stands preclinical development. Its pharmacology establishes what the compound does: its primary action on the target, its wider actions on other systems, studied as safety pharmacology, and the relationship between exposure and effect. Its pharmacokinetic work establishes absorption, distribution, metabolism and excretion, predicting whether a human dose can achieve the exposures that worked in the test systems. Its toxicology establishes the harms to watch for: single and repeated dose toxicity, effects on reproduction and development where relevant, genetic toxicity, and the margin between the exposure producing the wanted effect and the exposure producing harm, because that margin shapes the starting dose and the escalation plan of the first human study.

1.5 The investigational new drug application

The investigational new drug application, universally shortened to IND, is the application by which a sponsor asks the regulatory authority for permission to begin testing an unapproved drug in humans, and, in the United States system from which the term comes, to ship the investigational product for that testing. The application assembles the preclinical story in three parts: the chemistry, manufacturing and controls information establishing what the product is; the pharmacology and toxicology evidence, with its margins and target organs; and the plan for the first studies, the protocol and investigator brochure of Unit 3. In India, the corresponding permission to conduct a clinical trial of a new drug or an investigational new drug is given under the New Drugs and Clinical Trials Rules, 2019, by the Central Licensing Authority, on an application with the data and documents those Rules prescribe, and the ethics committee approval of Section 1.8 stands beside the regulatory permission as a separate, equally necessary gate. Two gates, two different questions: the regulator asks whether the national requirements for this trial are met, and the ethics committee asks whether this trial, at this site, with these participants, should be done at all.

1.6 Ethics in biomedical research: why ethics is structural, not decorative

Ethics in biomedical research is the discipline that governs research involving human participants, and the syllabus places it inside Unit 1, beside drug development, because it is a design input to every trial and not a clearance obtained at the end. The historical failures behind the safeguards, research on people who could not consent, risks concealed, vulnerable groups used because they were available, are assumed here from the neighbouring subjects. Each modern safeguard answers one of those failures, which is why the safeguards are not negotiable courtesies. For the Pharmacy Practice student, the practical translation is this: every operational topic in Units 3 to 5, the consent form, the ethics submission, the safety report, the monitoring visit, the audit, is an ethical safeguard wearing working clothes.

1.7 Principles of ethics in biomedical research

The principles are respect for persons, beneficence with non maleficence, and justice. Respect for persons means participants decide freely on full information, may withdraw without penalty, and receive added protection where autonomy is reduced. Beneficence and non maleficence mean risks are identified, minimised, monitored and justified by the expected knowledge. Justice means participants are selected for scientific reasons, with burdens and benefits shared fairly. Around them stand scientific validity, independent review, informed consent, confidentiality, accountability and transparency, and the continuing duty of care. An examination answer should name the principles and then show each one operating in a named trial activity: consent, review, monitoring, reporting.

1.8 The ethics committee: constitution

The ethical committee of the syllabus, called the ethics committee in Indian usage and the institutional review board in the American term the syllabus prints beside it, is the independent body that reviews and approves research involving human participants before it begins and monitors it while it runs. Its constitution

is prescribed because its independence and its competence both depend on who sits on it. In composition, the standard pattern across these frameworks is a chairperson drawn from outside the institution; a member secretary who organises its work; clinician and basic medical science members who can judge the science and the risks; a legal expert; a social scientist, ethicist or community representative who speaks for the participant and public perspective; and a lay person from the community, whose presence tests whether the documents and explanations make sense to a non professional.

1.9 Functions of the ethics committee and the review process

The functions of the ethics committee follow from its purpose, to protect the rights, safety and wellbeing of trial participants, across the whole life of a trial. Before the trial, it reviews the submission of Section 3.10: the protocol, for scientific soundness and the balance of risk and expected benefit; the investigator brochure, for whether known risks are honestly stated; the consent form and participant information, for completeness and plain language; recruitment and payments, for fairness and freedom from inducement; the arrangements for privacy, confidentiality, and care and compensation for research related injury under the applicable rules; and the investigator's qualifications and the site's facilities. Its decisions are to approve, to approve with modifications, to require changes and resubmission, or to disapprove, with reasons in writing; no participant may be enrolled before approval for that site exists. During the trial it reviews amendments before implementation, receives safety information and progress reports, conducts continuing review at intervals suited to the trial's risk, and can require changes, suspend or terminate its approval if the balance changes. After the trial it receives the completion report. Review is therefore a continuing oversight relationship, and the team's prompt, complete EC communications, which the monitor checks in Unit 4, are what make it real.

Ethics committee review across a trial



© 2026 PharmacoLearn, pharmacolearn.fyi

Figure: Ethics review across the life of a trial. Approval opens the gate, continuing review keeps it honest, and every decision is written.

1.10 Challenges in implementation of ethical guidelines

The challenges in implementation of ethical guidelines are the known failure points between the written standard and the working trial. The first is the consent gap: forms in technical language, translated poorly, or signed as a formality, so the signature exists and the understanding does not; the countermeasures are plain language documents, translation and back translation, time to decide, and staff trained to explain rather than to obtain signatures. The second is committee capacity: committees reviewing complex protocols without enough members, time, training or support produce delay or superficial review; the

countermeasures are the constitution and quorum disciplines of Section 1.8 and honest workload planning. The third is vulnerability and inducement: participants who are poor, ill, dependent on the treating doctor, or unfamiliar with research may agree for reasons that are not free choice. The fourth is the dual role of the treating clinician who is also the investigator, where trust in the doctor can blur the line between treatment and experiment; clear separation of the conversations is the standard protection.

1.11 ICH GCP guidelines in the conduct of clinical trials

The ICH GCP guidelines, the Good Clinical Practice guideline of the International Council for Harmonisation, reference E6, are the international standard for designing, conducting, recording and reporting trials involving human participants. GCP gives public assurance that the rights, safety and wellbeing of participants are protected, consistent with the principles of the Declaration of Helsinki, and that the trial data are credible. Its principles, at framework level, are these: trials follow the ethical principles originating in the Declaration of Helsinki, GCP and the applicable regulatory requirements; foreseeable risks are weighed against anticipated benefit before a trial begins, and it continues only while that balance remains favourable; the rights, safety and wellbeing of participants prevail over the interests of science and society; the available nonclinical and clinical information adequately supports the trial; trials are scientifically sound and described in a clear, detailed protocol; a trial complies with the protocol that received prior ethics committee approval; medical care and decisions rest with a qualified physician; everyone involved is qualified by education, training and experience; freely given informed consent is obtained before participation; trial information is recorded, handled and stored so it can be accurately reported, interpreted and verified; participant confidentiality is protected; investigational products are manufactured, handled and stored to good manufacturing practice and used as the protocol directs; and systems assuring the quality of every aspect of the trial are implemented. The current revision of E6 modernises the same framework for electronic systems and risk proportionate quality management; the principles above are its stable core.

1.12 ICMR guidelines in the conduct of clinical trials

The ICMR guidelines, the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants issued by the Indian Council of Medical Research, are the national ethical framework within which Indian trials, and Indian biomedical research generally, are designed and reviewed. Their practical chapters govern what an Indian committee actually decides: committee constitution and working, the consent process, research in vulnerable populations with named added protections, biological materials and data, and institutional responsibilities for oversight infrastructure. For a trial in India the frameworks meet in a triangle: the New Drugs and Clinical Trials Rules, 2019 supply the regulatory permission and committee registration requirements, ICH GCP is the working standard, and the ICMR principles are the ethical framework. A student who can place each document in that triangle understands the Indian system.

1.13 Drug safety reporting: the duty stated in outline

Drug safety reporting appears in Unit 1 of the syllabus because it is an ethical duty before it is a procedure. An adverse event is any untoward medical occurrence in a participant administered a product, whether or not it is considered related to that product; seriousness is a separate judgement on the outcome for the participant, and it drives the speed of reporting. When a participant is harmed, or new risk information emerges, the bodies charged with protecting participants must learn of it promptly and in a form they can act on. The investigator records events in the source documents and the case report form, assesses seriousness and, as the protocol requires, causality, treats the participant, and reports serious events to the sponsor and, as the applicable rules and the committee require, to the ethics committee within the timelines those instruments prescribe. The sponsor evaluates safety information across the whole programme, since a pattern invisible at one site may be unmistakable across many, reports expedited cases to the authority

and to investigators and committees as the rules require, and updates the brochure and, where needed, the consent documents when the risk picture changes. In India these duties sit inside the New Drugs and Clinical Trials Rules, 2019 framework. No timelines are reproduced here, deliberately: they are prescribed figures a working trial takes from the current rules and its protocol, and an examination answer is marked on the chain of duties, investigator to sponsor to authority and committee.

*More free M.Pharm notes and unit wise PDFs at pharmacolearn.fyi
Free video lectures on the PharmacoLearn YouTube channel*