Proclinical®
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The drug development process

The drug development process evaluates the findings from drug discovery and turns it into a safe and effective medical treatment for patients. Research into new drugs is usually prompted by new insights into a disease, existing treatments that have unexpected effects, the discovery of new technologies, or many tests of molecular compounds to find potential benefits to treat a range of diseases.

10-12

Developing a successful medicine takes on average 10 to 12 years, but this will often depend on funding

5,000 - 10,000

Around 5,000 - 10,000 compounds may be tested to achieve one successful medicine

1,000

For every 1,000 compounds that are initially tested, only one will make it to human trials.

Research & development

Regulatory process

The regulatory process involves showing relevant governing bodies that a drug is fit for purpose and makes a valuable contribution to health. The regulatory affairs team will advise at all stages of the process and give strategic advice on the legal and scientific requirements a drug must meet. They will be responsible for collecting, collating, and evaluating data, as well as being responsible for registration documents and carrying out any negotiations that affect a product's market authorisation. Additionally, a regulatory affairs department will often be involved in the development of product marketing concepts and is required to approve packaging and advertising before a product goes to market.

Discovery

At this early stage, thousands of compounds may be potential candidates for development as a medical treatment. Only a small number of compounds will be promising and will make it to further testing.

Pre-clinical & development

Once a compound is identified as promising, experts will study the potential benefits, the best dosage, the best way to administer the drug, its side effects, and much more to ensure that it safely passes all forms of preclinical testing. Due to safety, this stage of R&D can take many years to do successfully and can often prove to be very costly.
If a molecule shows promise, drug developers will usually patent it, preventing other companies from copying it. Once a patent on a drug has expired, generic versions (or biosimilars) of the drug can be produced.

Clinical

Clinical research (Phases I-III)

The clinical trial process is split into three main phases. The earliest phase trials may look at whether a drug is safe, what dosage is best and what side effects it causes. Later phase trials aim to test whether a new treatment is better than existing treatments.

Phase I	● ○ ○ ○ ○	1-80 healthy participants
Phase II	● ● ○ ○ ○	100-300 participants with condition
Phase III	● ● ● ● ●	1000+ participants with condition

Clinical operations

The clinical operations team will ensure proper planning, conduct, patient safety, and data quality, while nurturing good communication between study sites and sponsors.

Medical affairs

Medical affairs professionals will be responsible for having input and providing support to the clinical trials process. Their learnings in the clinical stage will help them to formulate the provision of information that is used in subsequent publications and to educate the wider medical community.

HEOR & market access

Once the initial clinical trials are complete, the HEOR and market access teams will work with the regulatory team to find the best way to get the drug approved. Health economic experts will use a variety of models to collect and analyse data that will lead to the most cost-effective and equitable use of resources in healthcare. Market access will then ensure that patients will be able to easily access the drug and confirm it's marketed at a reasonable price that is in line with the medication's effectiveness.

Drug safety / pharmacovigilance

During clinical trials, the medicine is assessed and evaluated to understand more about the risks and benefits it provides. Safety monitoring of medicines is a continuous process and continues even after the medicine has been approved for general use.

Biometrics

Before, during, and after the clinical trial is complete, the data and findings will be reviewed to ensure the safety and efficiency of the trials.

Manufacturing

Production

The pharmaceutical manufacturing process is typically made up of a combination of specific unit processes, chosen according to the physical and chemical characteristics of the drug. For each batch there is a unique process that will normally involve granulation, coating, blending and filling, tablet pressing and packaging. The steps in this process will vary depending on the make-up of the drug.

Quality control

Quality control will ensure every batch meets the correct standard. This includes checking the product for conformity and ensuring it is of the right quantity. The control of quality is an essential process and should be applied at all manufacturing stages, starting with the design, through to assembly of raw materials, in-process, post-process and finally the finished product.

Quality assurance

Quality assurance specialists will make sure products are safe, fit for purpose and consistently of a high standard. The team will ensure the process meets Good Manufacturing Practice (GMP) compliance and review the effectiveness of the process.

Validation

Validation is a requirement of pharmaceutical regulating agencies such as the FDA in the US or EMA in Europe, and the GMP guidelines.
Once approved by the quality department, the validation team will establish documentation that demonstrates that the process meets the level of compliance at all stages. In the drug development process it is important that the process is consistent and will produce the same result every time, which is why the systems and equipment will also be validated.

Commercial

Marketing & sales

Once the product has been approved by regulatory bodies and has the correct marketing licence for that country or region, it is ready to be marketed and distributed to healthcare providers. The marketing department will ensure the brand is represented clearly and that healthcare professionals and patients understand the benefits and risks of each treatment. They will be responsible for finding new ways to drive business improvement and deliver greater value to patients and consumers. The sales team will then use the resources provided by marketing to sell to hospitals, pharmacies, and other healthcare providers. Sales reps play a vital role in educating and influencing healthcare professionals and key opinion leaders on the advantages of the drug over other products on the market.

Repositioning

After a medicine has been approved, the clinical trials will continue to find out if the treatment can be used to treat other diseases by accessing its effectiveness as well as looking at the long-term benefits and safety

Safe monitoring

Even though vital information on a drug's efficacy and safety is researched in clinical trials, it is impossible to have all the information about the safety of a drug when it is approved. Therefore, the full picture of a product's safety evolves over the months and even years ahead.
Post-marketing safety monitoring (also referred to as phase IV of the clinical trials process) checks the drug's performance in real life scenarios to study the long-term risks and benefits and to uncover any rare side effects.