MERCK

The journey of a molecule: from the lab to patients

Creating a medicine or vaccine is a journey, always with patients in mind. It includes the work of many people — from scientists, data analysts and clinical trial volunteers to manufacturing, regulatory, development, marketing and commercial teams, among many others.

Moving from molecule to market requires innovation, expertise, tenacity and agility.

01 | Discovery

Discovery is the process of exploring new and unique molecules, compounds and biologics that have potential to treat or prevent disease. We consider variables such as disease prevalence, unmet medical needs and current treatment options when identifying a preclinical candidate (PCC).

Discovery fact

It takes about

10 years

for a new product to reach the marketplace after the initial discovery.

02 | Preclinical

Preclinical testing uses a systematic approach to analyze and optimize a PCC to validate that it is safe and effective for use in clinical trials in the target population.

During this phase, the active pharmaceutical ingredient (API) is produced to create the product that will be supplied for the clinical studies.

Preclinical fact

1 in every 5,000

compounds that enter discovery and progress to preclinical development actually become an approved drug.

03 | Clinical

Clinical studies determine the safety and efficacy of our products by gathering evidence through testing and analysis in trial volunteers — first in healthy volunteers, then in those with the disease. Once we have sufficient safety and efficacy data, we file an application with the information we know about the product — including study data, analyses and reports — with a regulatory agency (such as the U.S. Food and Drug Administration) for approval.

Clinical fact

Less than 12%

of investigational medicines that enter clinical testing make it to approval.

04 | Manufacturing

Manufacturing is the process of industrial-scale production, packaging and distribution of our medicines and vaccines. The process varies from product to product but is always in full compliance with all regulations and Good Manufacturing Practices (GMPs) based on both U.S. and international requirements to ensure a compliant, reliable supply for our patients.

Manufacturing fact

GMP regulations

outline the minimum quality standards for manufacturing and vary by country. Each country has its own agency to monitor meeting the regulations and requirements.

05 | Commercialization

Once a product is approved and manufactured, we promote it — including through education and awareness campaigns — to customers, including physicians, health care providers, pharmacies, patient populations, wholesalers and governments. With a customer- and data-focused approach, we develop a brand strategy to create a unique impression for each product.

Commercialization fact

Marketing teams are key to creating the campaigns to educate stakeholders (customers) about the

Efficacy and Safety

of our products to ensure appropriate use.

06 | Post-marketing

Post-marketing begins following the approval of a product, when it is released to the market. It includes activities to monitor and evaluate the product for safety and efficacy in a real-world setting.

Post-marketing fact

Companies monitor approved medicines for as long as they are on the market to:

- Meet regulatory reporting requirements
- Provide internal reporting for ongoing analyses
- Supply data to expand the lifecycle of the product