Pharmaceuticals Europe

From molecule to medicine creating new medicines

Molecular Discovery Research

The first step in creating new medicines is finding chemical compounds. Scientists in GSK's Molecular Discovery Research teams identify and validate targets for new medicines – such as receptors and enzymes. After targets are identified, highly sophisticated, automated technologies are put to use in screening large chemical libraries against them. As a large company, GSK is able to meet the capital investment required to support these manufacturing-scale drug discovery efforts.

These "screens" identify the most promising chemicals which can go on to be developed into potential lead compounds by the Centres of Excellence for Drug Discovery, GSK's "biotech-like" portion of the drug development process.

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The Centres of Excellence for Drug Discovery

The Centres of Excellence for Drug Discovery (CEDDs) generally focus on specific disease areas. At no more than 300-400 people, a CEDD group is nimble and entrepreneurial. Each CEDD is responsible for identifying the targets of most relevance in its therepeutic area and building on the lead compounds to produce a potential medicine.

CEDD scientists and clinicians collaborate with colleagues across R&D to ensure that all our efforts are directed toward transforming the compounds with the greatest potential into medicines. For example, research is conducted in pre-clinical development to evaluate the safety and metabolic outcome of compounds in laboratory animals, prior to testing in humans. This testing is mandated by law and regulated by government agencies.

The most promising compounds are selected as candidate medicines and progressed to clinical trials. Early trials, called Phase I trials, typically involve healthy volunteers. These trials study the safety of the compound and its interaction with the body, such as its concentration and duration in the blood. Interaction with other medications is studied to ensure that there are no ill-effects if a patient is already having treatment for another condition.

Phase II studies involve a small number of patients who have the illness that the compound is designed to treat. Early Phase II trials seek to provide preliminary evidence that the compound is effective and well tolerated for the target disease – called "proof of concept". A positive proof of concept underpins the investment needed to move to larger Phase II and Phase III trials.

Medicines development

Creating a medicine requires that we:

- test the compound to confirm quality, safety and efficacy
- register the compound with regulatory authorities
- monitor its use as a medicine.

Driving these activities are our Medicine Development Centres (MDCs) which focus on evaluating potential medicines in specific disease areas. These activities are highly regulated. Data are collected, analysed and summarised to prepare the regulatory files necessary to gain approval for use in countries throughout the world.

If Phase II results have been encouraging, Phase III trials, the largest part of a clinical development programme, go forward. These trials, often involving thousands of patients worldwide, are designed to provide the substantial evidence of efficacy and safety required to enable regulatory agencies to approve a medicine for wider patients' use. The prescribing information ultimately approved by these agencies, following their own analyses, directs the appropriate use of the medicine.

Trials of a medicine often continue after approval, called Phase IV trials. These trials further evaluate the effect of the medicine for the approved use, assess other potential uses or provide additional safety data. The company can also start new clinical trial programmes for other possible indications.

Given the exploratory nature of clinical development, investigators often need to conduct trials of varying designs to determine the potential of an investigational medicine and how it can be used appropriately. Rarely does any one trial enable a full understanding. Although pharmaceutical companies design and take responsibility for the trials they sponsor, any clinical-development programme ultimately depends on the commitment of physician-investigators and the patients they enrol in clinics and hospitals.

Careful planning is incorporated into every step to make certain that we are protecting the patients enrolled in the trials, meeting regulatory requirements, assessing a product's commercial viability and ultimately developing medicines which offer patients meaningful benefit.

Our commitment

We employ over 15,000 staff in research and development worldwide and our scientists are discovering the secrets of health and disease. We bring to this quest not only the talents of our scientists, but also the resources of a large company devoted to scientific enterprise. Our efforts are driven by a sense of urgency and by the realisation that our work helps millions of people around the world. As part of this effort, we conduct 65 million screenings for new medicines each year in the search for new medicines.

Our pipeline

Since 2000 GSK has been researching and developing a wide range of medicines and we have increased the number of new chemical entitis in our pipeline by over 80%. We are progressing clinical trials in type 2 diabetes, asthma, malaria, AIDS, rheumatoid arthritis, bacterial infections, Parkinson's disease, stroke, schizophrenia, Alzheimer's disease, depression, osteoporosis, inflammatory bowel disease and various cancers including breast cancer.

We are also a world leader in the development of vaccines and have clinical trials under way for pandemic flu, AIDS, dengue fever and malaria, whilst a vaccine against the causes of cervical cancer was recently submitted to the European Agency for the Evaluation of Medicinal Products (EMEA).

Key facts

- GSK has a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer
- We are a research-based pharmaceutical company and employ over 15,000 staff in research and development worldwide
- Every hour GSK spends more than €435,000 on finding new medicines
- In Europe we are spending over 1.4 billion on research and development in areas such as asthma, diabetes, pain relief, COPD, heart disease and cancer
- We believe GSK remains the only pharmaceutical company researching both new vaccines and treatments for HIV/AIDS, TB and malaria – the World Health Organization's three priority diseases.

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For more information please see gsk.com/pipeline/index.htm