# HOW **IDEAS** BECOME **MEDICINES**

Global collaboration helps bring new drugs to patients.

## THE DISCOVERY PROCESS

Researchers around the world study diseases to find out what causes illness, and new treatments that might improve and save lives. In a long process of elimination, scientists make discoveries—natural products that already exist, or new compounds made in a lab—that they think will make a difference to people with a disease. This process can take years. Once a new candidate looks promising, it must pass pre-clinical testing to make sure it's safe to try in people.

## SAFETY IS JOB #1

A pharmaceutical company must seek permission from government regulators like the FDA or EMA to test the new candidate medicine in humans. The drug then begins the three phases of clinical trials. Patient safety is always the top priority and many candidates will not make it through this process.

## THE PHASES OF CLINICAL RESEARCH

A pharmaceutical company will often contract with clinical research and technology organizations to set up and run clinical trials. These companies work with doctors and nurses to identify and recruit patients for the clinical trials, collect and analyze patient data and look for unwanted side effects.

Phase I trials are the first step. They are usually small studies, sometimes just 10–30 people, and focus on safety and understanding how the drug moves through the body.

Phase II trials are larger. These studies look at how well the medicine works, understanding what dose may be needed and what side effects may occur.

Phase III trials are much larger, focusing on safety and effectiveness in a wide range of people.

Clinical research and technology companies and their pharmaceutical company partners are constantly evaluating safety and effectiveness and adapting clinical trials to new information to streamline development. When clinical trials are completed, regulators review all the data that has been collected. Only drugs that have proven to be safe and effective may be approved.

## LAUNCHING A NEW MEDICINE

Once approved, the pharmaceutical company will manufacture and distribute the medicine so it can be used to treat and cure diseases. Even after a new drug reaches the market, clinical research and technology companies continue to monitor its safety and effectiveness.

## HELPING PEOPLE LIVE LONGER, HEALTHIER LIVES

The clinical trial process can take 3–6 years or more. It may involve thousands of people around the world, cost more than a billion dollars, and have stops, starts and failures. Clinical research companies help new treatments get to patients sooner and more efficiently.

Drug development may result in patients just taking one pill a day. But bringing a new medicine to patients is anything but simple.

## HOW DO CLINICAL RESEARCH & TECHNOLOGY COMPANIES SUPPORT CLINICAL TRIALS?

Clinical research and technology organizations provide a wide range of clinical trial, laboratory, data and other support services for the pharmaceutical industry as they evaluate new medicines. Drug companies choose to work with specialized partners because they have confidence that their trials will be conducted safely and efficiently. Each year, clinical research and technology companies employ over 130,000 people and conduct the vast majority of clinical trials around the world. These organizations make trials faster and less expensive, helping patients get faster access to new medicines.

## THE STEPS OF **CLINICAL TRIALS**

**Rigorous testing must take place to ensure the safety and effectiveness of new medicines.**

**PRE-CLINICAL LABORATORY RESEARCH**

3–6 YEARS

**CLINICAL TRIALS**

3–6 YEARS

**PHASE I**

SAFETY IN PEOPLE

**PHASE II**

SAFETY, DOSING, EFFECTIVENESS

**PHASE III**

SAFETY, EFFECTIVENESS

**DATA REVIEW & APPROVAL**

6 MONTHS–2 YEARS

**POST-APPROVAL MONITORING & RESEARCH**

SAFETY, EFFECTIVENESS

ACRO member companies contribute to all aspects of drug development, with a focus on Phase I–III clinical trials and laboratory services.