

THE FIVE STEPS IN DRUG DEVELOPMENT



Drug development is a long, expensive process. RDCA-DAP seeks to accelerate the process, reduce the cost and improve success rates.

DISCOVERY AND DEVELOPMENT

Following research on the basic nature of a disease, laboratory studies are conducted to discover a potential treatment (discovery) and better understand it (development).

PRECLINICAL RESEARCH

Before experimental treatments can be tested in people, they undergo laboratory and animal testing.

CLINICAL RESEARCH

Phase 1: Testing is conducted among a small number of healthy volunteers to determine safety.

Phase 2: Testing is conducted in a small number of volunteers who have the disease to evaluate both safety and effectiveness.

Phase 3: Testing is expanded to a larger number of people with the disease to further establish safety and effectiveness.

Researchers submit a **New Drug Application (NDA)** to FDA for approval.

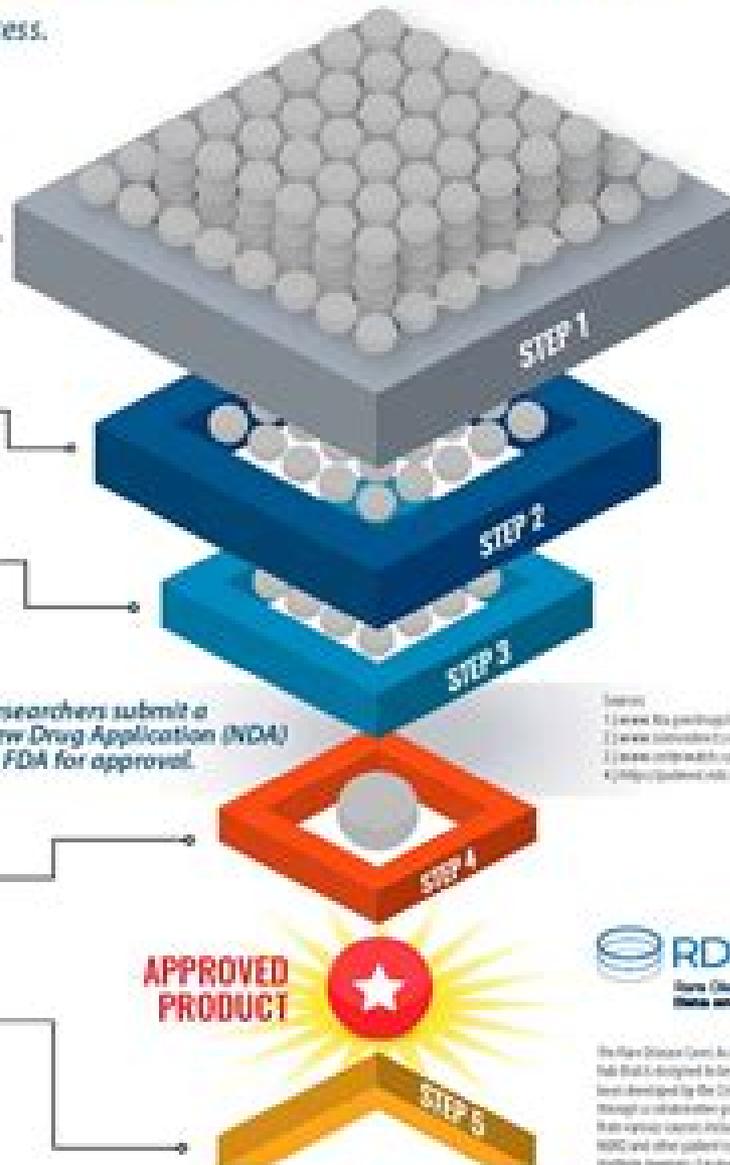
US FOOD AND DRUG ADMINISTRATION (FDA) REVIEW

FDA review teams thoroughly examine all the submitted data and decide whether to approve the product.

POST-MARKETING SAFETY MONITORING

After products are approved and made available to the public, FDA continues to monitor them for safety.

To learn more, visit: rarediseases.org/rdca-dap



DID YOU KNOW?

On average, of **5,000** potential treatments that enter pre-clinical testing, **only 5** are tested in humans and **only 1** is approved.

It takes an average of **12 years** for an experimental drug to progress from pre-clinical research to approval.

About **14%** of drugs entering clinical trials will ultimately be approved.

Recent estimates of the cost of developing a new prescription drug range from **\$2.14 billion** to **\$2.8 billion**.

Source:

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