THE FIVE STEPS IN DRUG DEVELOPMENT

NORD®

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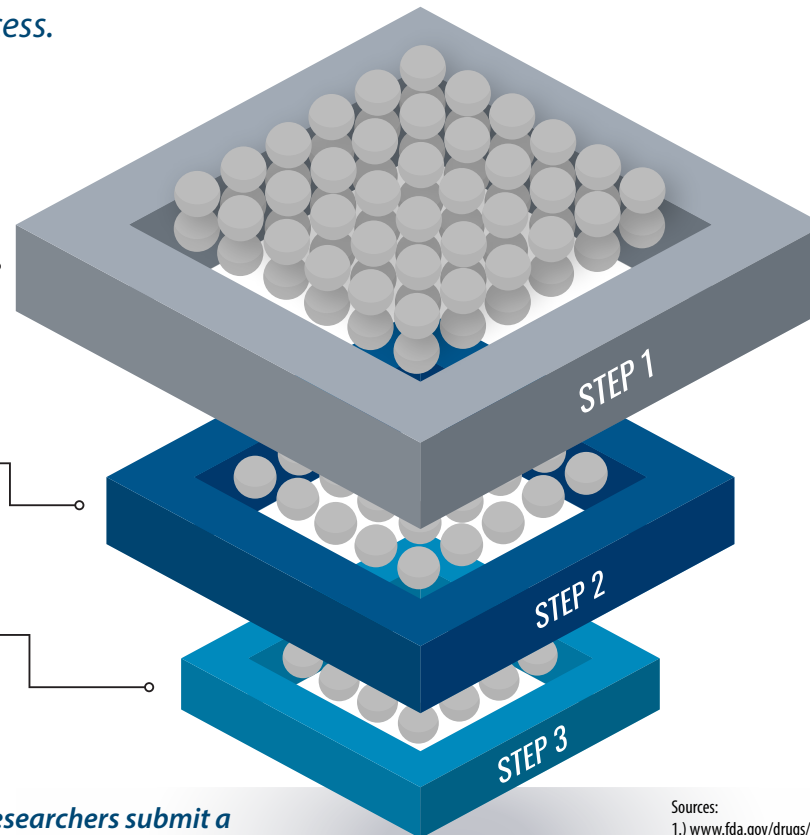
Phase 3: Testing is expanded to a larger number of people with the disease to further establish safety and effectiveness.

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.

STEP 1

STEP 2

STEP 3

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

STEP 4

STEP 5

APPROVED PRODUCT >

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 **$314 million** to **$2.8 billion.**

Sources:
1.) www.fda.gov/drugs/information-consumers-and-patients-drugs/beginnings-laboratory-and-animal-studies
2.) www.sciencedirect.com/science/article/pii/S2452302X1600036X
3.) www.centerwatch.com/articles/12702-new-mit-study-puts-clinical-research-success-rate-at-14-percent
4.) https://pubmed.ncbi.nlm.nih.gov/32125404/

RDCA-DAP®
Rare Disease Cures Accelerator
Data and Analytics Platform

CRITICAL PATH INSTITUTE

The Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP) is an integrated database and analytics hub that is designed to be used in building novel tools to accelerate drug development across rare diseases. It has been developed by the Critical Path Institute (C-Path) and the National Organization for Rare Disorders (NORD) through a collaborative grant from the U.S. Food and Drug Administration (FDA). Data for the platform is shared from various sources including clinical data from industry, research data from academics, patient registry data from NORD and other patient registry sources willing to share. Types of accepted data will continue to expand as the platform develops. For more information, visit c-path.org/rdca-dap. NRD-2246