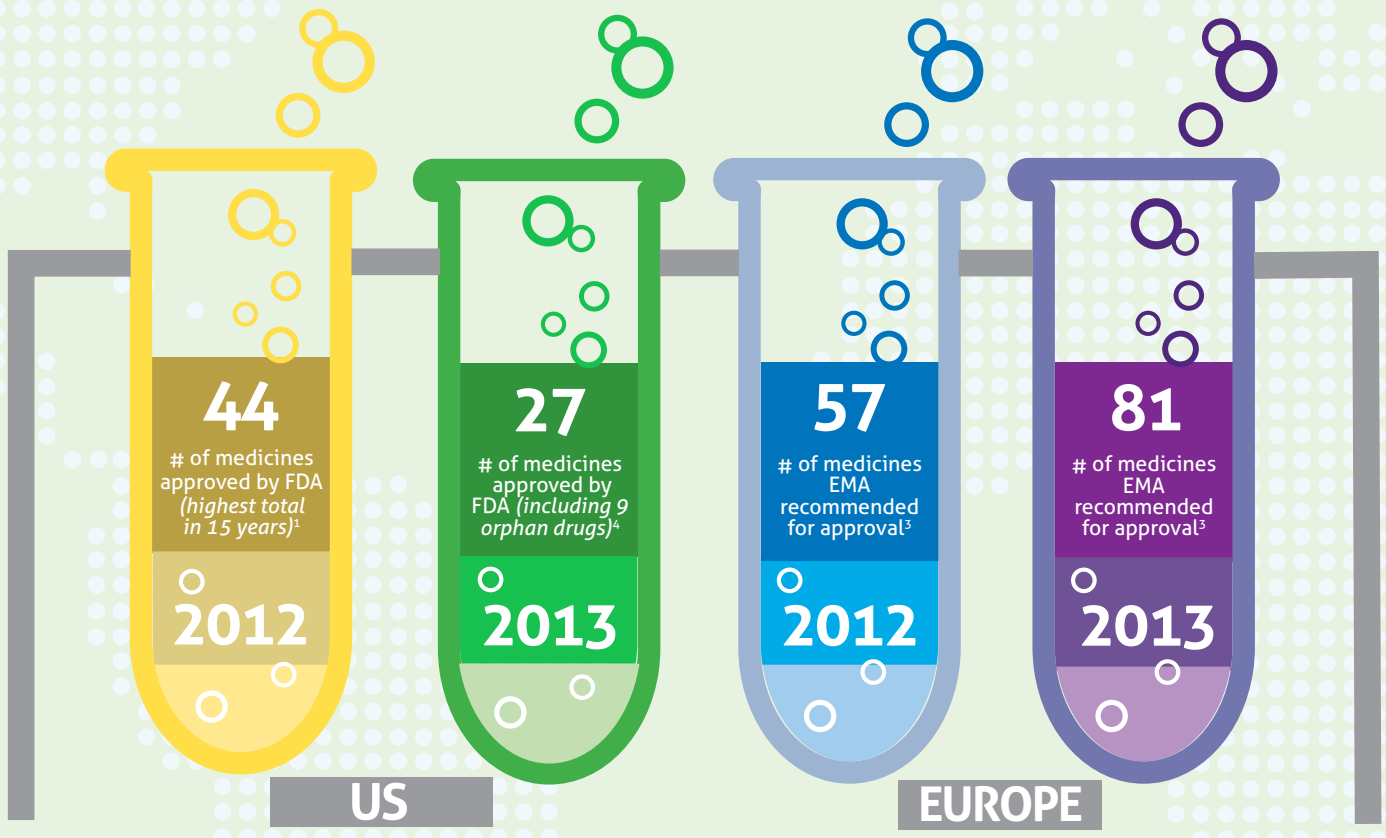
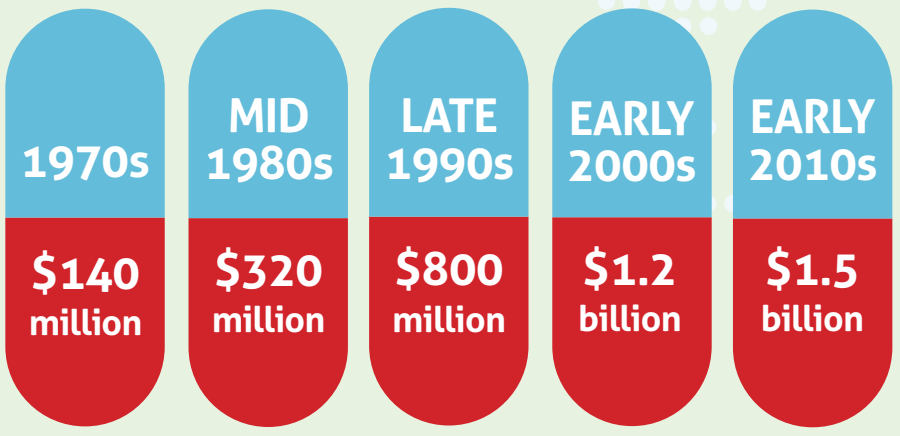
# Mapping a Path to Market: Creating a Comprehensive Drug Development Strategy

## OVERVIEW »

FOR EVERY **5,000** to **10,000** COMPOUNDS ENTERING THE PIPELINE, **ONLY ONE** WILL MAKE IT TO MARKET.[1]

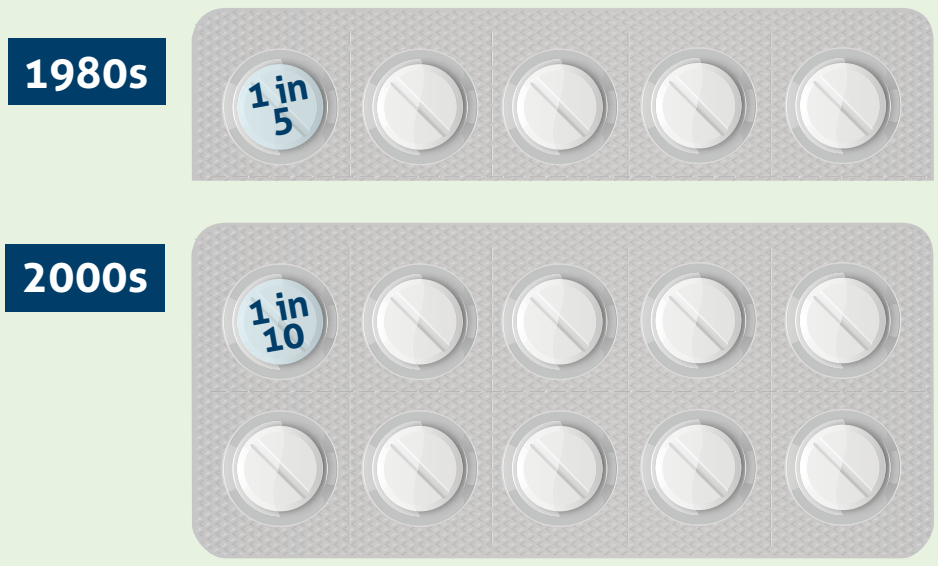



## AVERAGE COST TO DEVELOP A DRUG (INCLUDING COST OF FAILURES)[1, 2] »



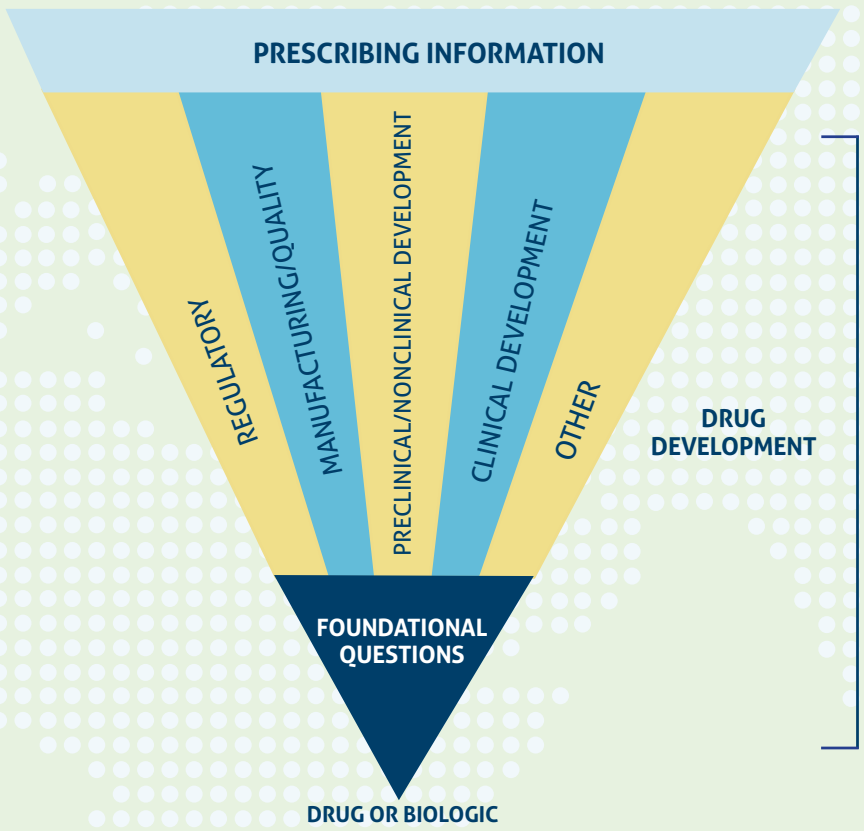

## SUCCESS RATES FOR DRUGS IN CLINICAL DEVELOPMENT [2] »

**ARE FALLING SUCCESS RATES PARTLY TO BLAME?**




## THE FOUNDATION OF A COMPREHENSIVE DRUG DEVELOPMENT STRATEGY »

**DRUG DEVELOPMENT** HAS BEEN DESCRIBED AS THE PROCESS OF OBTAINING THE INFORMATION **YOU WANT** TO BE INCLUDED ON YOUR DRUG'S PRESCRIBING INFORMATION. AT THE BOTTOM TIP IS THE DRUG ITSELF, AND ACROSS THE BROAD TOP IS THE PRESCRIBING INFORMATION. EVERYTHING IN BETWEEN IS DRUG DEVELOPMENT.




## THREE FOUNDATIONAL QUESTIONS »

FORM THE BASE OF A **COMPREHENSIVE DRUG DEVELOPMENT STRATEGY** BY CONSIDERING THESE QUESTIONS.

**What is the end goal?**
- GETTING YOUR DRUG TO MARKET?
- LICENSING YOUR COMPOUND?

**What are the desired product attributes?**
- INDICATION/USAGE & DOSAGE?
- ADMINISTRATION & PHARMACOLOGY?
- ADVERSE REACTIONS & TOXICOLOGY?
- CLINICAL DATA?

**Where will the drug be marketed?**
- UNITED STATES?
- EUROPE?

## THE FOUNDATION OF A COMPREHENSIVE DRUG DEVELOPMENT STRATEGY »

### DISCOVERY
- 2-10 years
- Biopharma companies with the assistance from universities and labs search for a "lead compound" that has the possibility to alter the course of the disease

**COMPOUND IDENTIFIED**

### DEVELOPMENT

**PRECLINICAL**
- 2-6 years
- Studies not performed on humans
- To establish safety before the drug is given to humans

**SUBMIT IND**
Need FDA's approval to test on humans

**PHASE I**
- 1-2 years
- 1st human test
- 12 to 40 subjects; healthy volunteers
- Establish profile & dosing regimens
- Assess safety & tolerability

**PHASE II**
- 2-3 years
- 20 to 400 subjects; with the target disease
- Establish proof-of-concept
- Test safety in affected patients

**PHASE III**
- 3-4 years
- 300 to 1,500 subjects; with the disease
- Prove safety & efficacy
- Establish long-term safety

**APPROVAL**
NDA/BLA submission

### POST-APPROVAL

**MANUFACTURING/QUALITY**

Who ? When ?
What ? How ?
Where ?

**OTHER**
- Intellectual property
- Reimbursement
- Marketing

SOURCES: 1. Pharmaceutical Research and Manufacturers of America. 2013 Profile: Biopharmaceutical Research Industry. July 2013. Available at:http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf. 2. Levine, Daniel S. New Estimate of Drug Development Costs Pegs Total at $1.5 Billion. December 7, 2012. Available at:http://www.burrillreport.com/article-new_estimate_of_drug_development_costs_pegs_total_at_1_5_billion.html.3. King, Simon. FirstWord Lists FDA drug approvals in 2013: Cause for industry optimism? January 5, 2014. Available at:http://www.firstwordphar-ma.com/node/1180426#axzz-2v0iLd7Dz. 4. Novel New Drugs 2013 Summary. Federal Food and Drug Administration Center for Drug Evaluation and Research. Available at: http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM381803.pdf

CLINIPACE WORLDWIDE