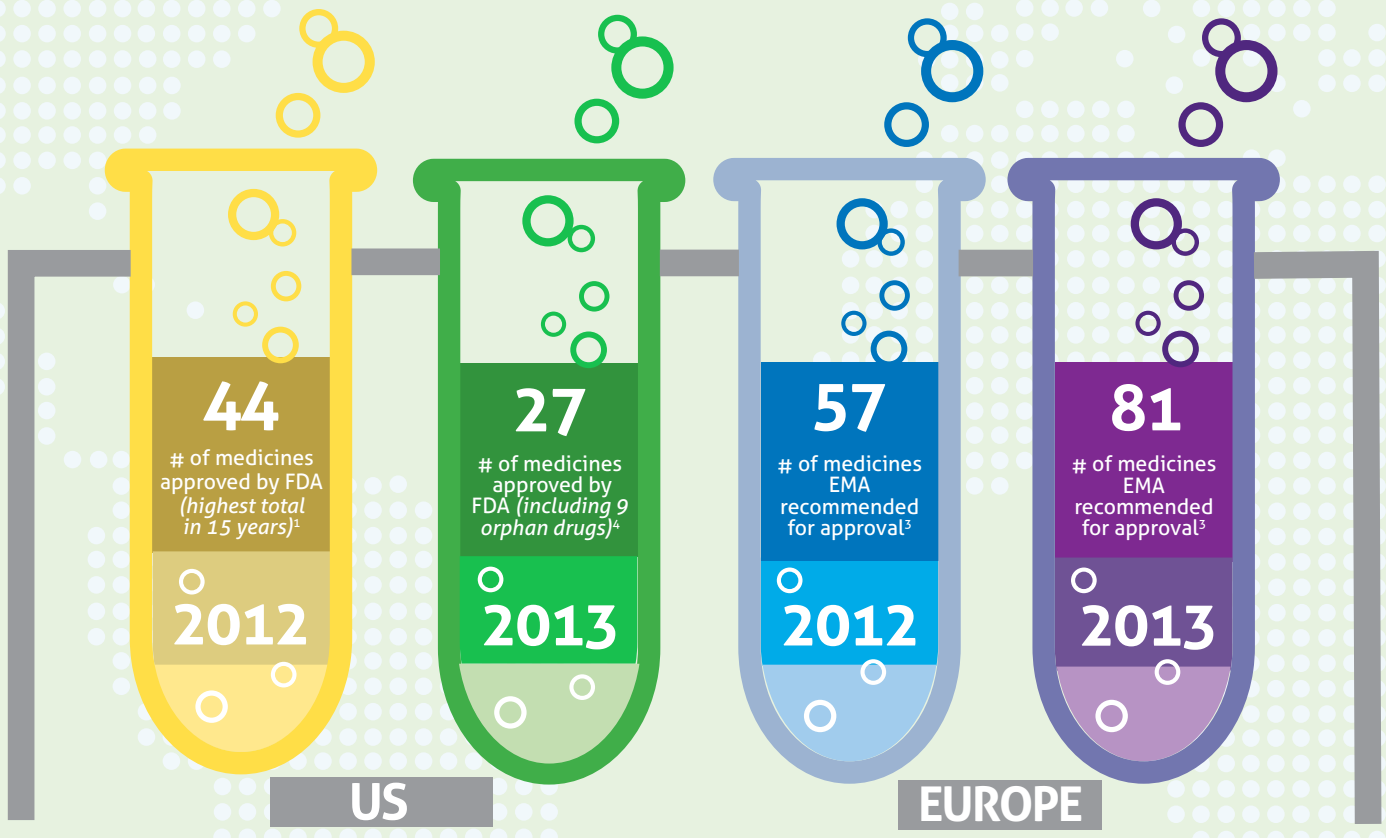
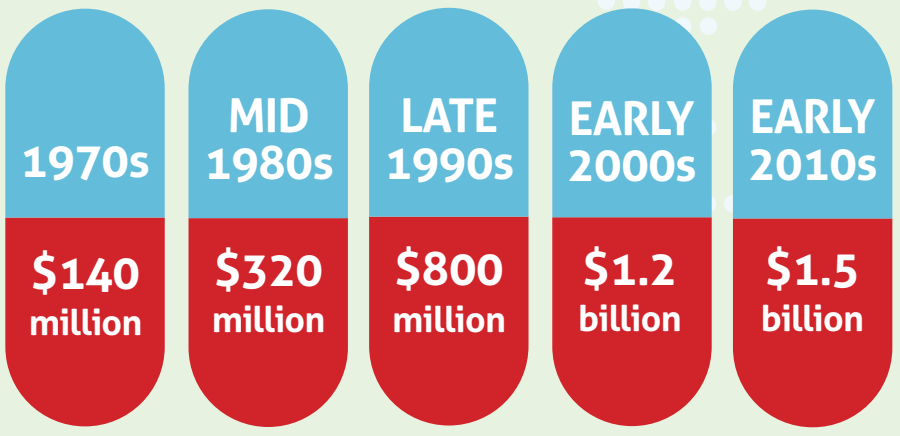
Mapping a Path to Market: Creating a Comprehensive Drug Development Strategy

OVERVIEW »

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

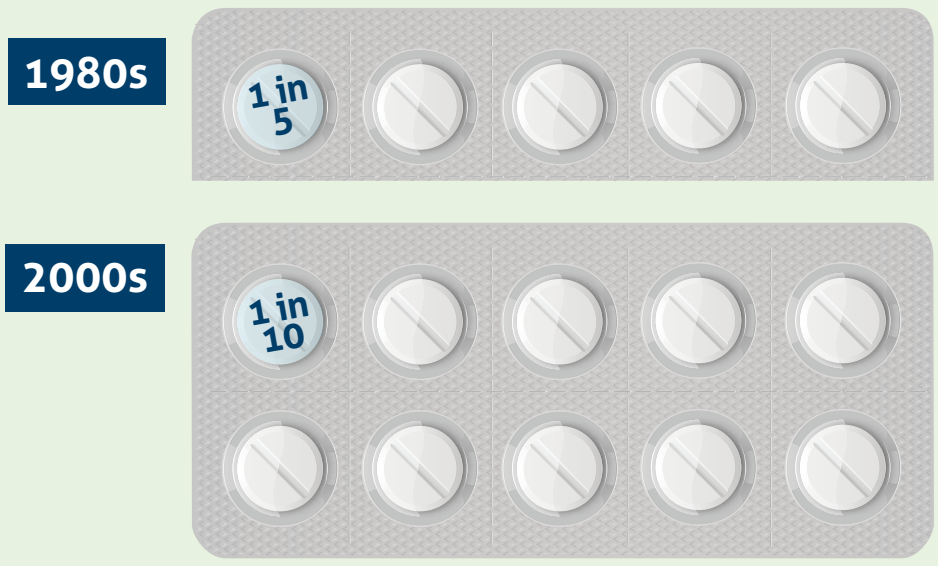


AVERAGE COST TO DEVELOP A DRUG (INCLUDING COST OF FAILURES)[1, 2] »



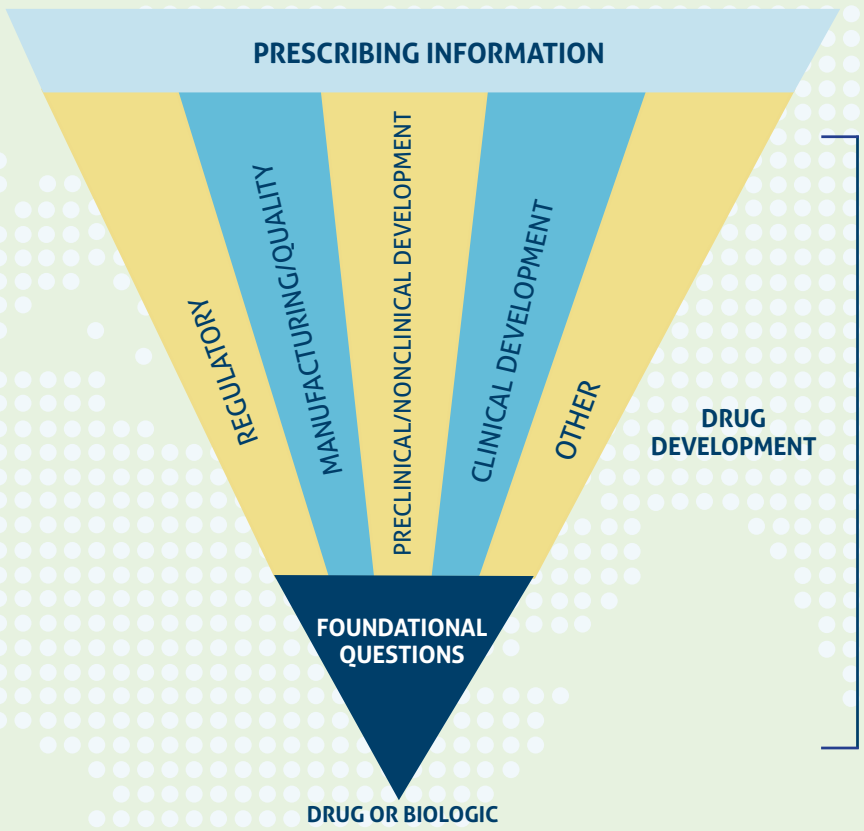
SUCCESS RATES FOR DRUGS IN CLINICAL DEVELOPMENT [2] »

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