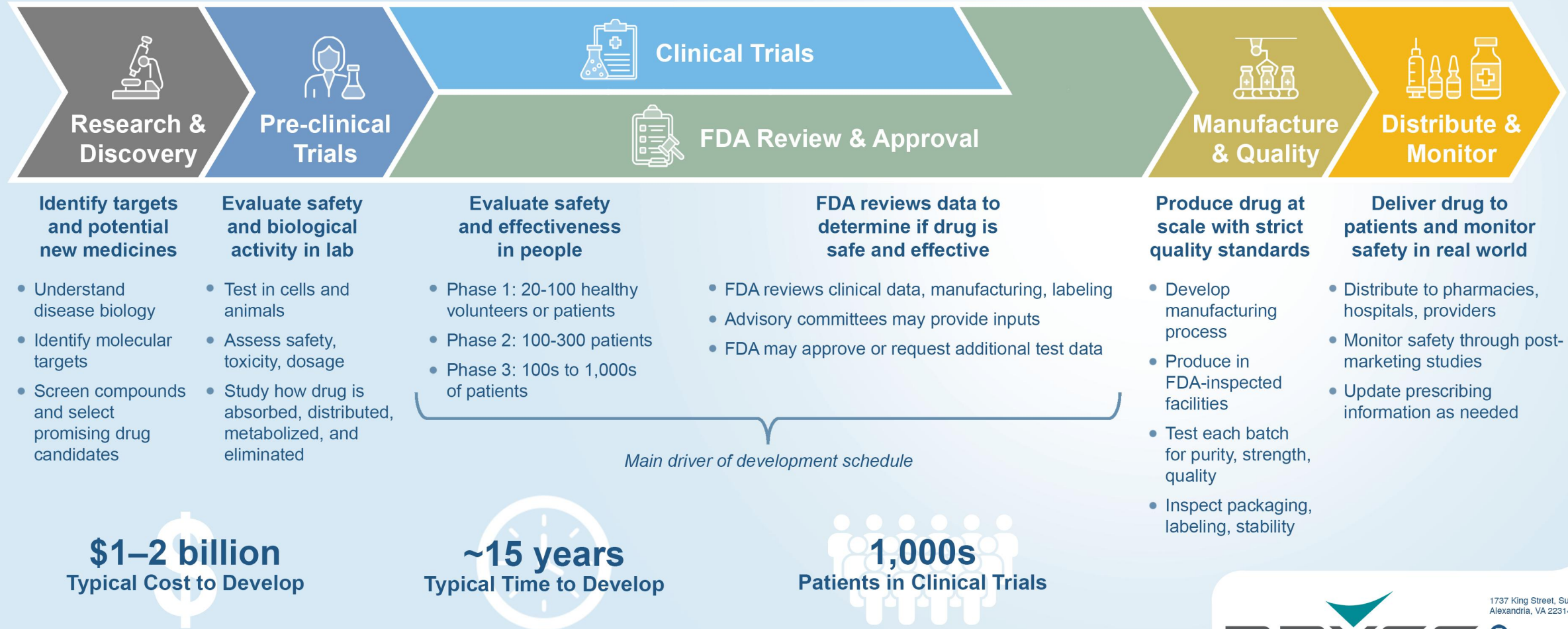




Emerging Opportunities Through Platform Drug Development

How Biologic and Synthetic Drugs are Developed in the United States

Drug development typically follows one of two processes: grown and synthesized. Each development stage is designed to ensure medicines are safe, effective, and of high quality.



Sources: U.S. Food & Drug Administration (FDA), National Institutes of Health (NIH), Tufts Center for the Study of Drug Development, JAMA Network Open, Nature Reviews Drug Discovery, NCBI.
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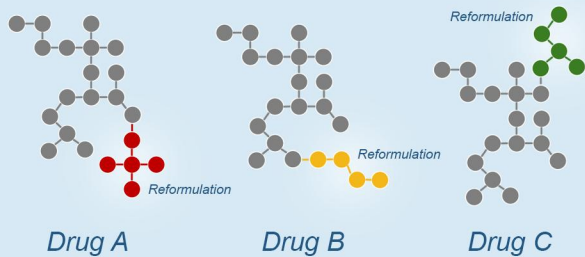
Emerging Opportunities Through Platform Drug Development

A new small molecule approach saves time, money, and ultimately, lives

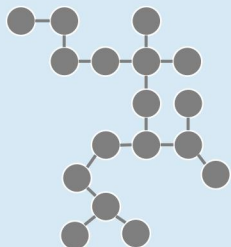
Small Molecule Platform Approach

This is a new platform technology process that leverages existing safety data and reformulates molecules, quickly developing new drugs. Advantages include:

- Adapting a new drug (reformulation) takes as little as weeks to target new indications
- Safety data can be re-applied to cut approval time by years
- Advantageous for on-shore production and distributed biomanufacturing (drug substance produced on demand)



Standardized FDA-approved Platform



Standardized

Manufactured to a precise standard and highly controlled

Modular

Different combinations produce entirely different products

Reusable

The same pieces are used repeatedly rather than reinvented

Scalable

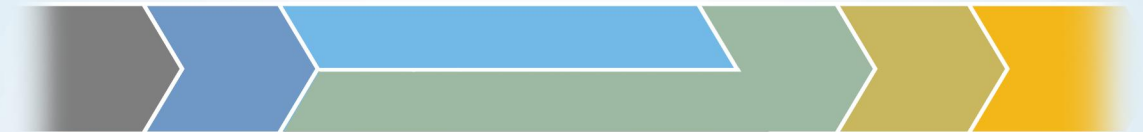
Once system exists, creating a new model is generally faster than creating the first one

Expandable

New blocks can be introduced without changing entire system

Typical Development Process

Emphasizes discovering something entirely new



\$1–2 billion
Typical Cost to Develop

~15 years
Typical Time to Develop



Drugs Developed Using Small Molecule Platform

Emphasizes building on something already proven



\$300–800 million
Typical Cost to Develop

~2 years
Typical Time to Develop

Platform technologies expand the drug development toolkit, enabling some therapies to be developed more efficiently while complementing, not replacing, traditional approaches.

Sources: U.S. Food & Drug Administration (FDA), National Institutes of Health (NIH), Tufts Center for the Study of Drug Development, JAMA Network Open, Nature Reviews Drug Discovery, NCBI.
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1737 King Street, Suite 601
Alexandria, VA 22314

703.647.8078

brycetek.com

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