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**U.S. FOOD & DRUG  
ADMINISTRATION**

CENTER FOR DRUG EVALUATION & RESEARCH



**FDA'S BIOMARKER QUALIFICATION PROGRAM  
EDUCATIONAL MODULE SERIES—MODULE 2**

# **HOW BIOMARKERS CAN IMPROVE THE DRUG DEVELOPMENT PROCESS**

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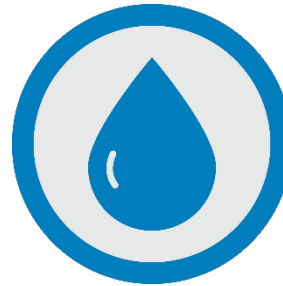
# BIOMARKERS IN HEALTH CARE AND RESEARCH

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## Health Care



Blood pressure



Blood glucose

## Research



Tumor markers in  
cancer research



Interleukins in  
inflammation research



# IMPROVING DRUG DEVELOPMENT

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## Drug Development Continuum



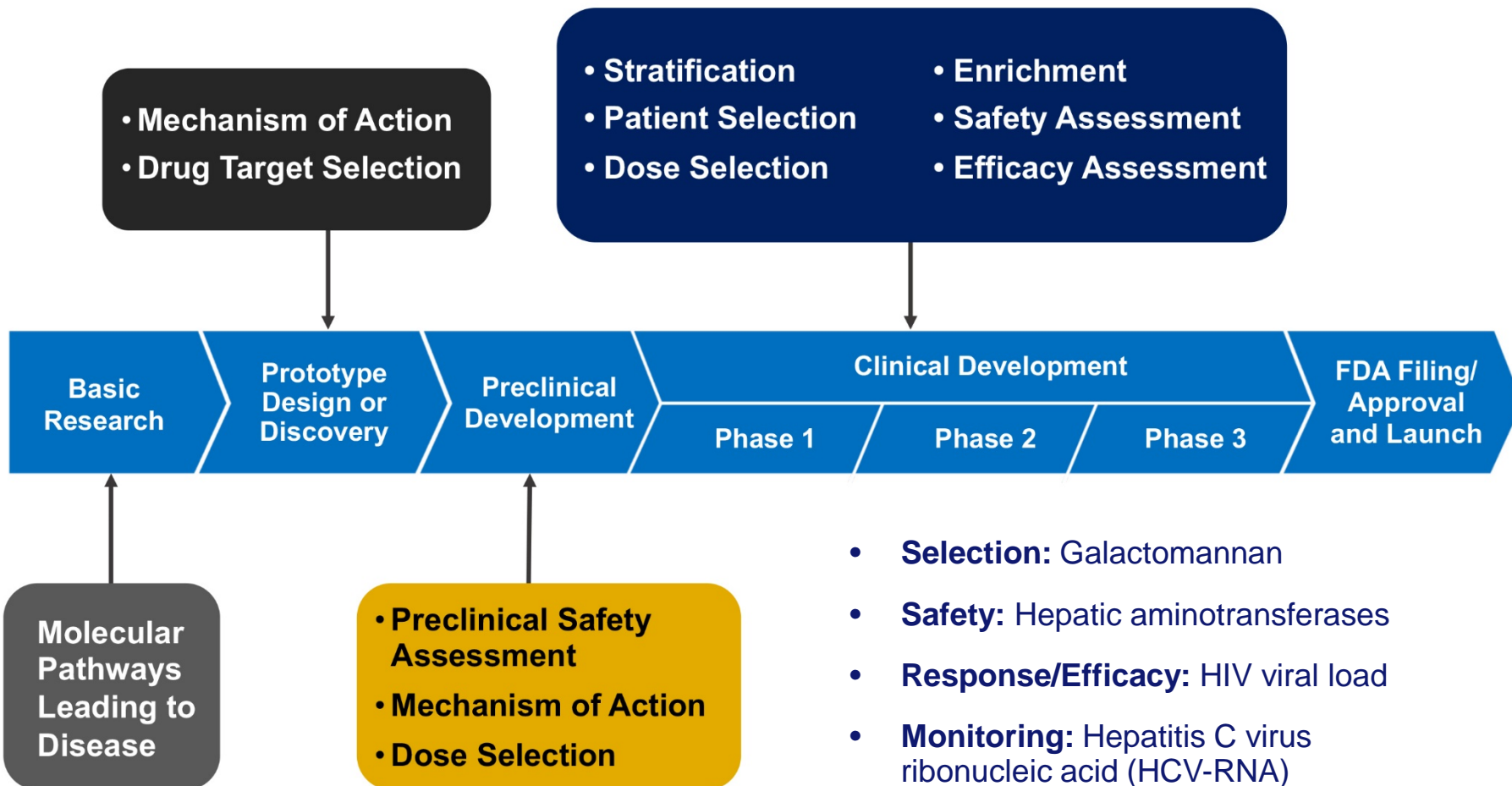
## Biomarkers can:

- Monitor the safety of a therapy
- Determine if a treatment is having the desired effect on the body
- Predict patients who might respond better to a drug from a safety or efficacy perspective
- Potentially enable time and cost savings in clinical trials



# BIOMARKERS: DRUG DEVELOPMENT

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# BIOMARKERS USED AS OUTCOMES

## Conventional approach:

- Measures performance of novel therapies using clinical outcomes, such as mortality or disease progression.
- Accruing enough information for clinical endpoints may take many years.

## Biomarker-driven approach:

- Biomarkers can sometimes predict drug efficacy more quickly than conventional clinical endpoints.
- Potential to accelerate product development in certain disease areas.



## Examples of Biomarkers Used as Outcomes in Development of FDA-Approved New Molecular Entities (NMEs) and New Biological Therapeutics (October 2007 to December 2015)



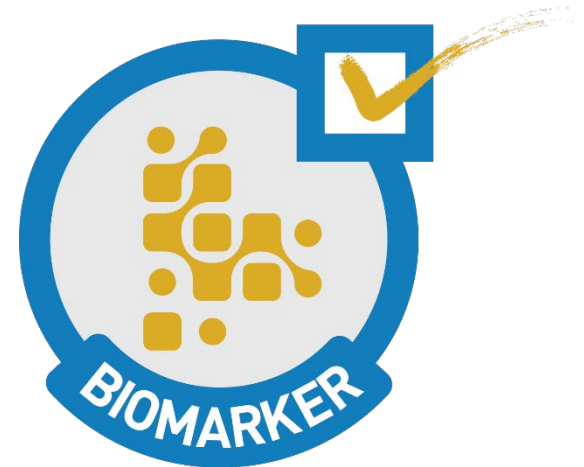
Therapeutic Area	Biomarker
Anesthesiology	T1*; magnitude of T4/T1* ratio by acceleromyography
Cardiology	Blood pressure
	Serum low-density lipoprotein (LDL-C)
Hematology	Hemoglobin
	Platelet count
	Ecarin clotting time; activated partial thromboplastin time; thrombin time; activated clotting time; plasma diluted thrombin time
	Serum ferritin
Infectious Disease	Hepatitis C virus (HCV) RNA*
	Human immunodeficiency virus (HIV)-1 RNA
	Sputum culture conversion to negative
	Parasite count resolution

Access the full table: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm483052.htm>



# BIOMARKER QUALIFICATION PROGRAM

- **Concept:** CDER developed the Biomarker Qualification Program to make biomarker data publicly available by establishing a biomarker's value for a particular context of use in drug development and regulatory review.
- **Regulatory implication:** No need to resubmit extensive data and request that the CDER review group reconsider or reconfirm the biomarker.





**LEARN MORE**

[www.fda.gov/BiomarkerQualificationProgram](http://www.fda.gov/BiomarkerQualificationProgram)