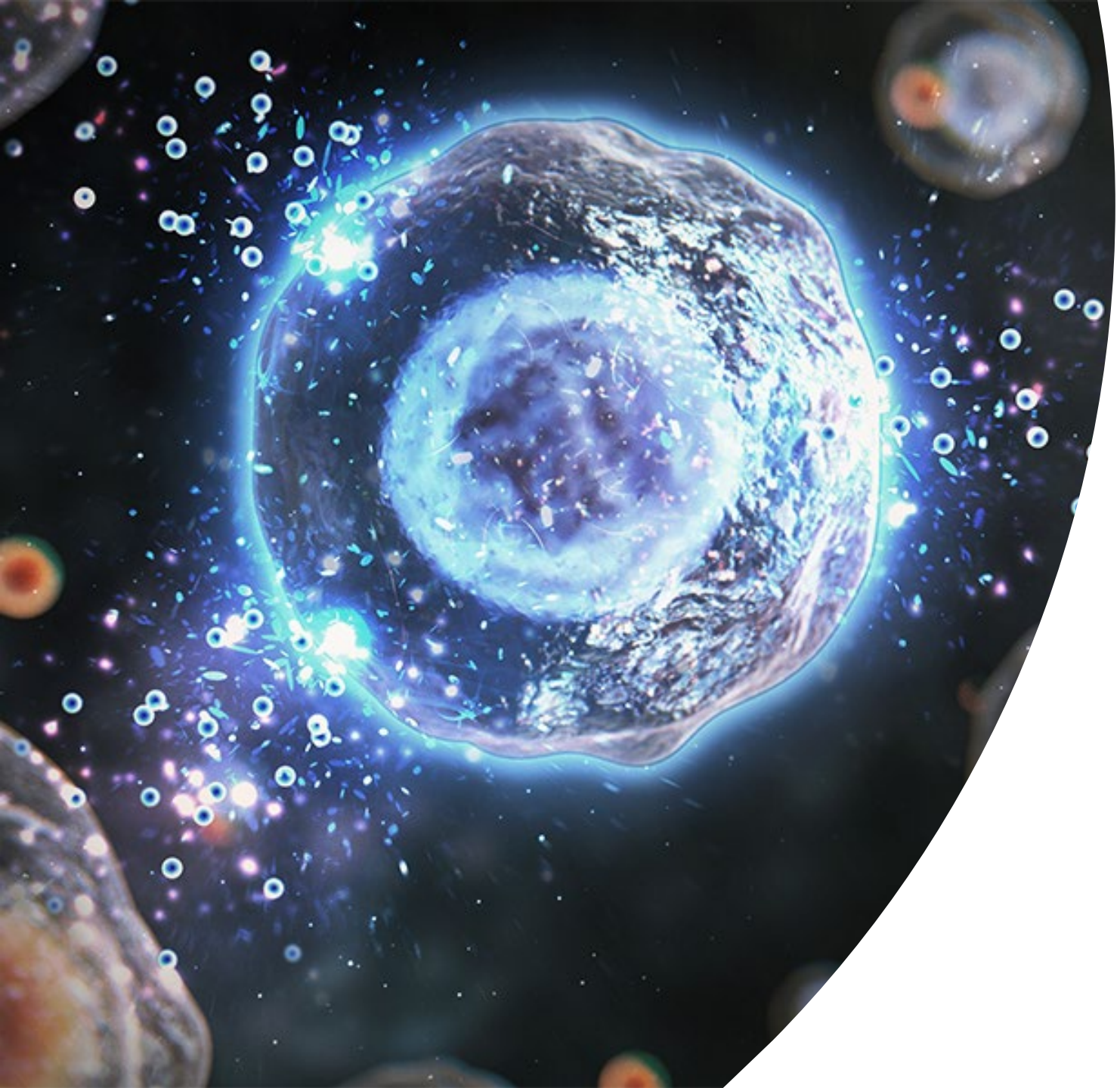

E11 –

Lecture 12: Considerations in Drug Disc. & Devel.

23/05/2025
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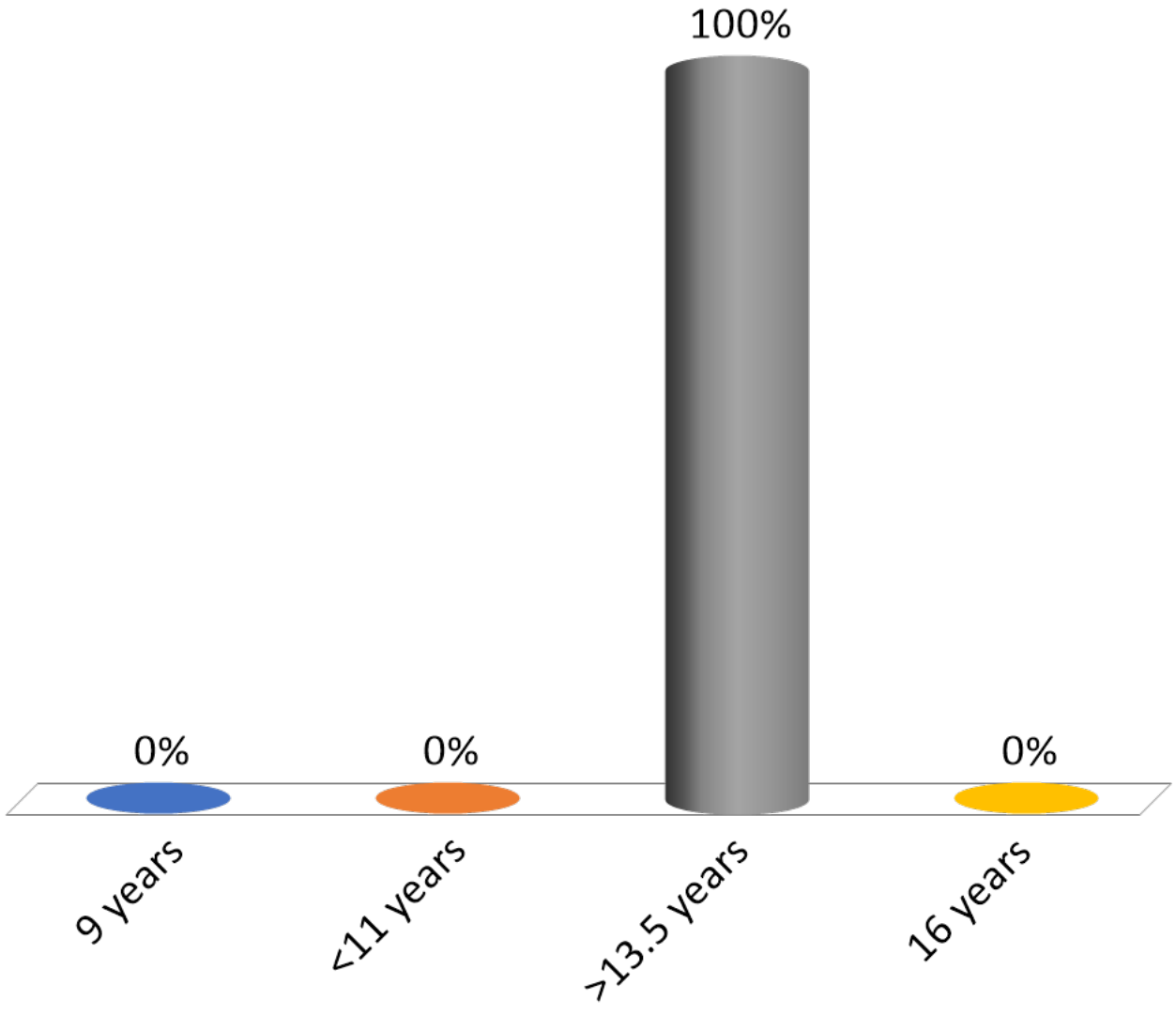
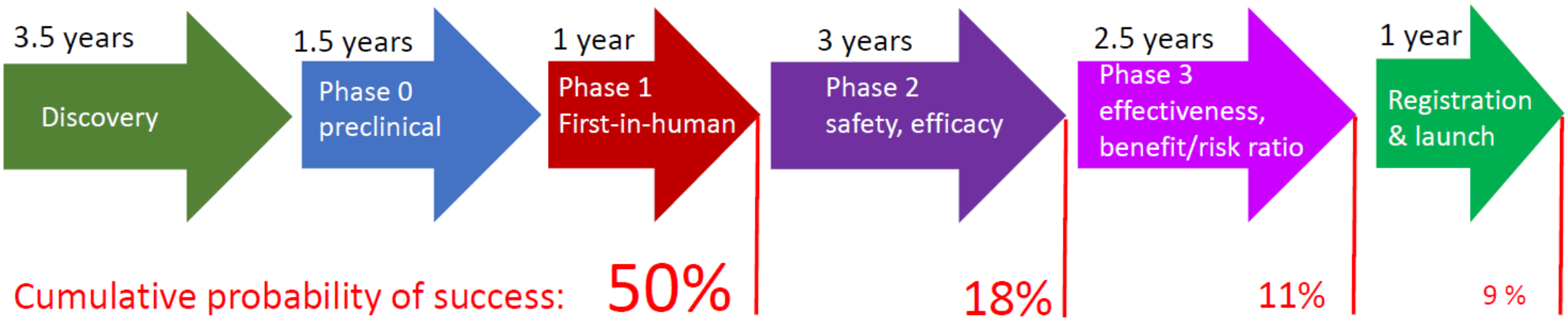
Q1: How long does it take to develop a drug on average?

A. 9 years
B. <11 years
✓ C. >13.5 years
D. 16 years



Drug development is a high risk, expensive journey



EUROMILLIONS

Odds of winning the jackpot: 1 in 139 million

1 single combo ticket costs CHF 3.50

CHF 486 500 000 will buy all combinations

Record jackpot 210 million (in Switzerland)!

Ten times riskier than Euromillions…

FTL SCIENCE		Average Time (Years)	Average Cost 2022 (US$ million)
Early Drug Discovery		2.5	353
Lead Optimization		2	562
Pre-Clinical Trials		1	340
Clinical Trials	Phase I	1.5	63
	Phase II	2.5	119
	Phase III	2.5	344
FDA Review and Approval		1.5	3
Total		> 13.5 Years	1784

But the Jackpot is much bigger and lives may be saved !

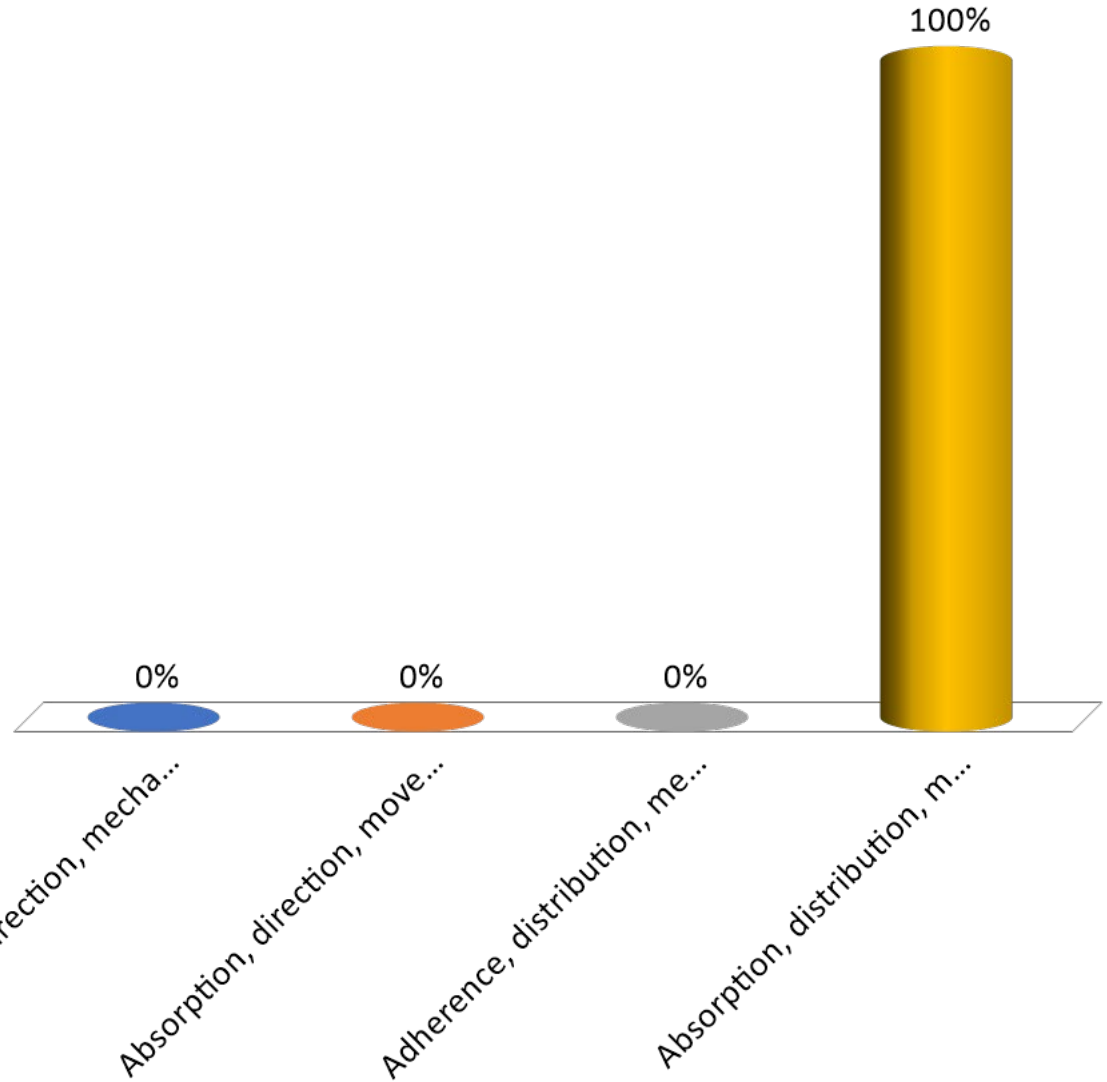
Q2: What does ADME stand for in the context of pharmokinetics (PK)?

A. Adhesion, direction, mechanics, and exclusion

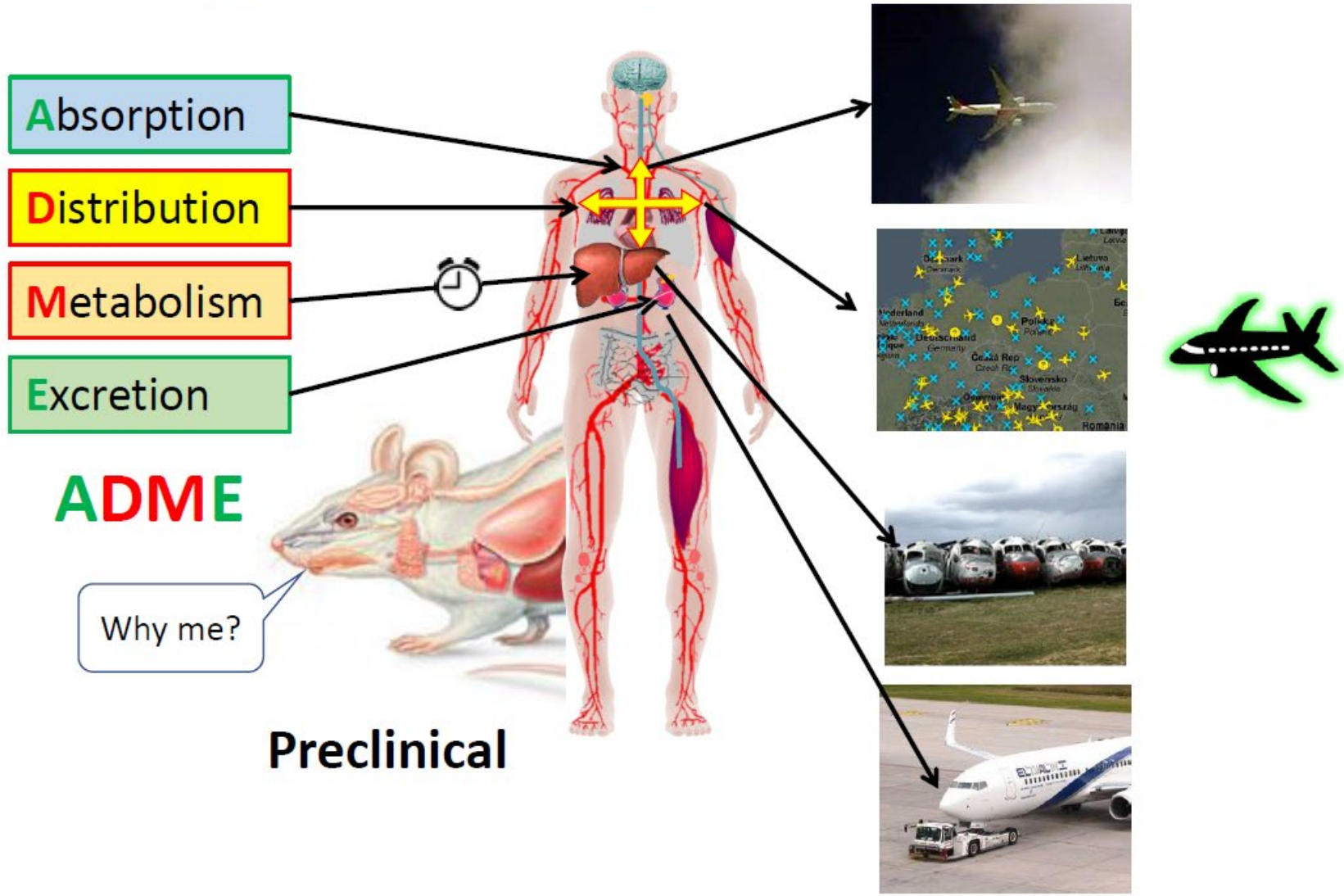
B. Absorption, direction, movement, excretion

C. Adherence, distribution, metabolism, excretion

✓ D. Absorption, distribution, metabolism, excretion



Pharmacokinetics (PK):
What happens to the drug inside the body?



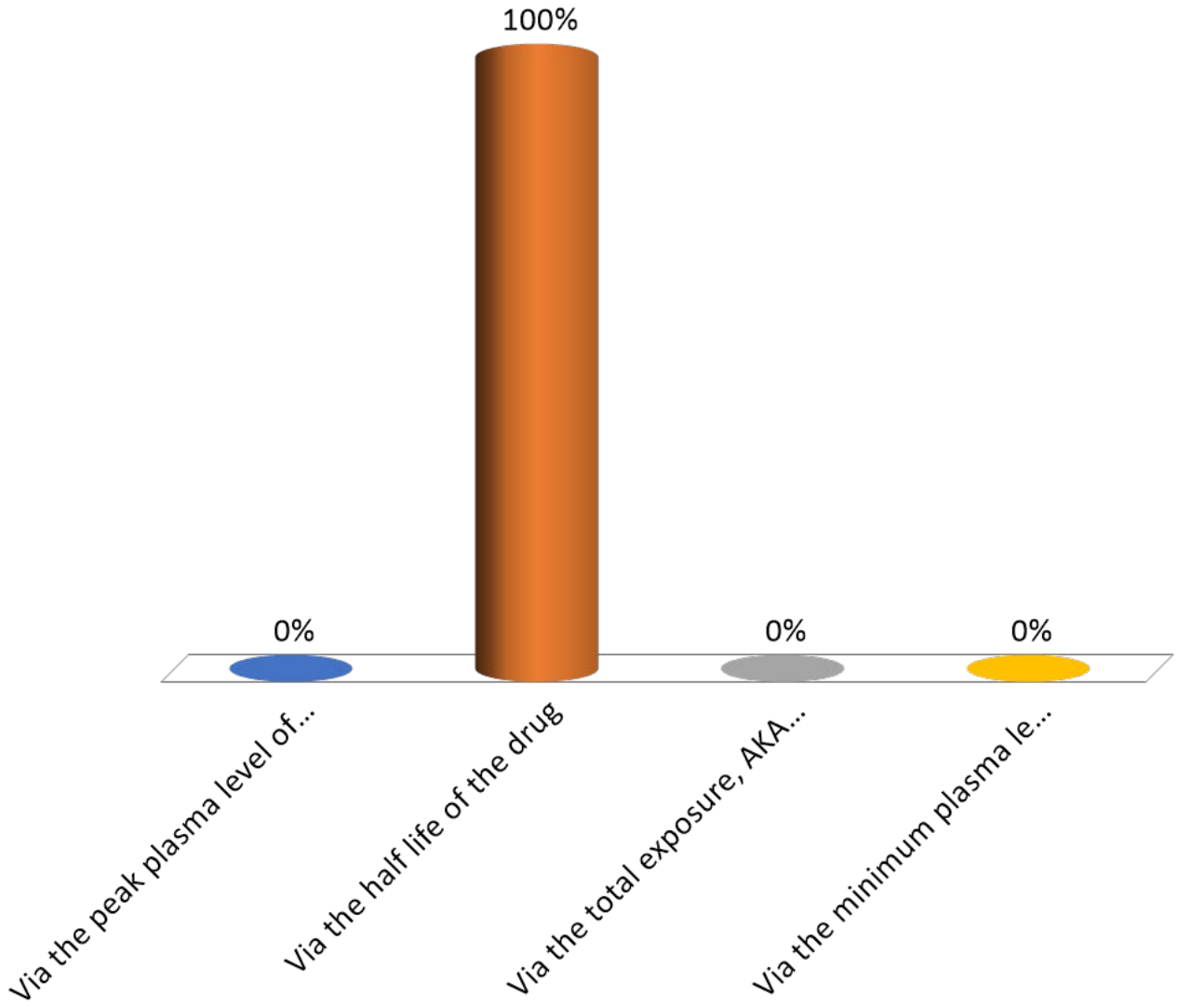
Q3: How do you determine how often a drug should be administered?

A. Via the peak plasma level of the drug

✓ B. Via the half life of the drug

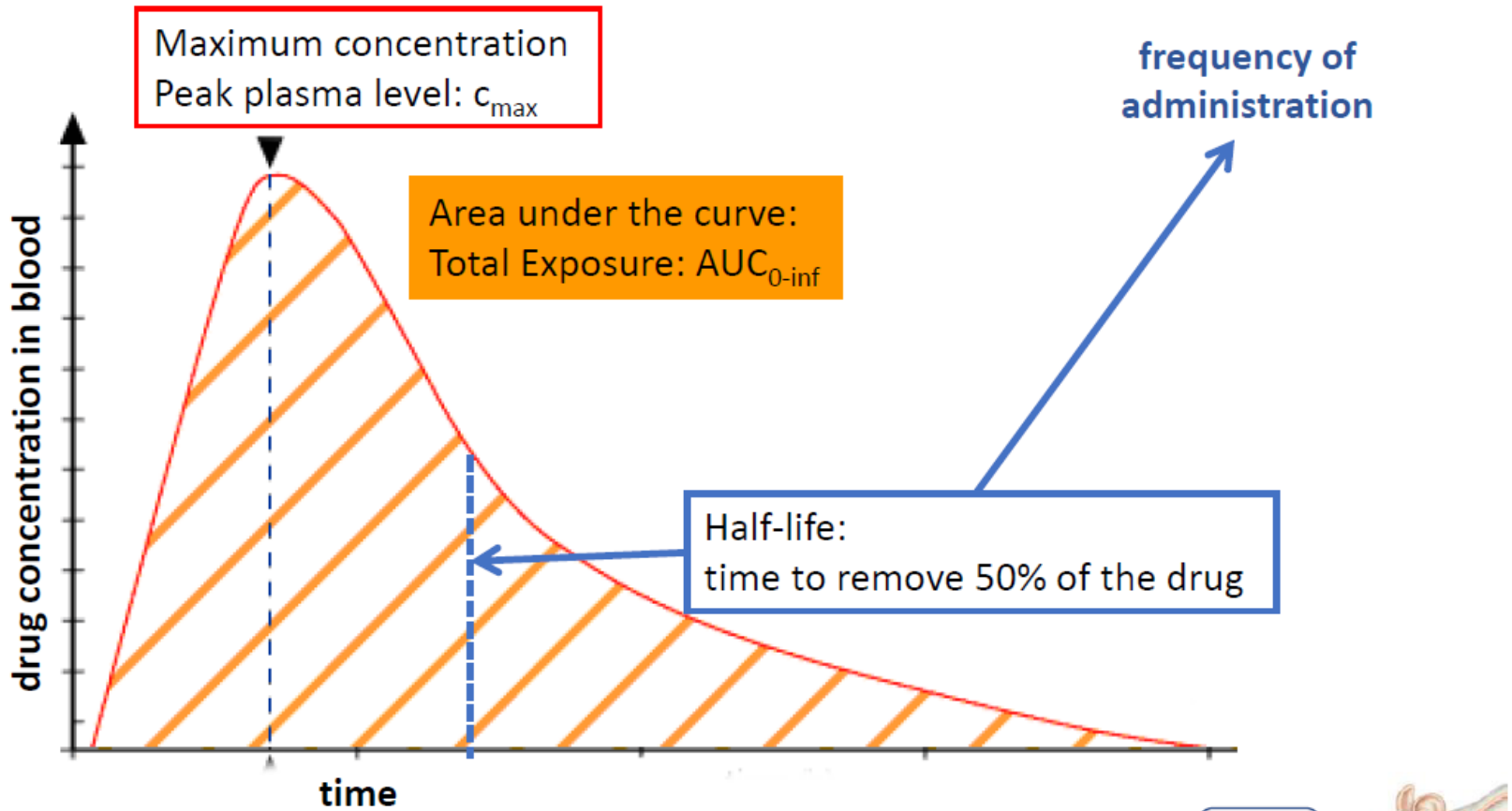
C. Via the total exposure, AKA the area under the curve

D. Via the minimum plasma level of the drug



What is Absorption?

(aka how does the drug travel into the bloodstream?)



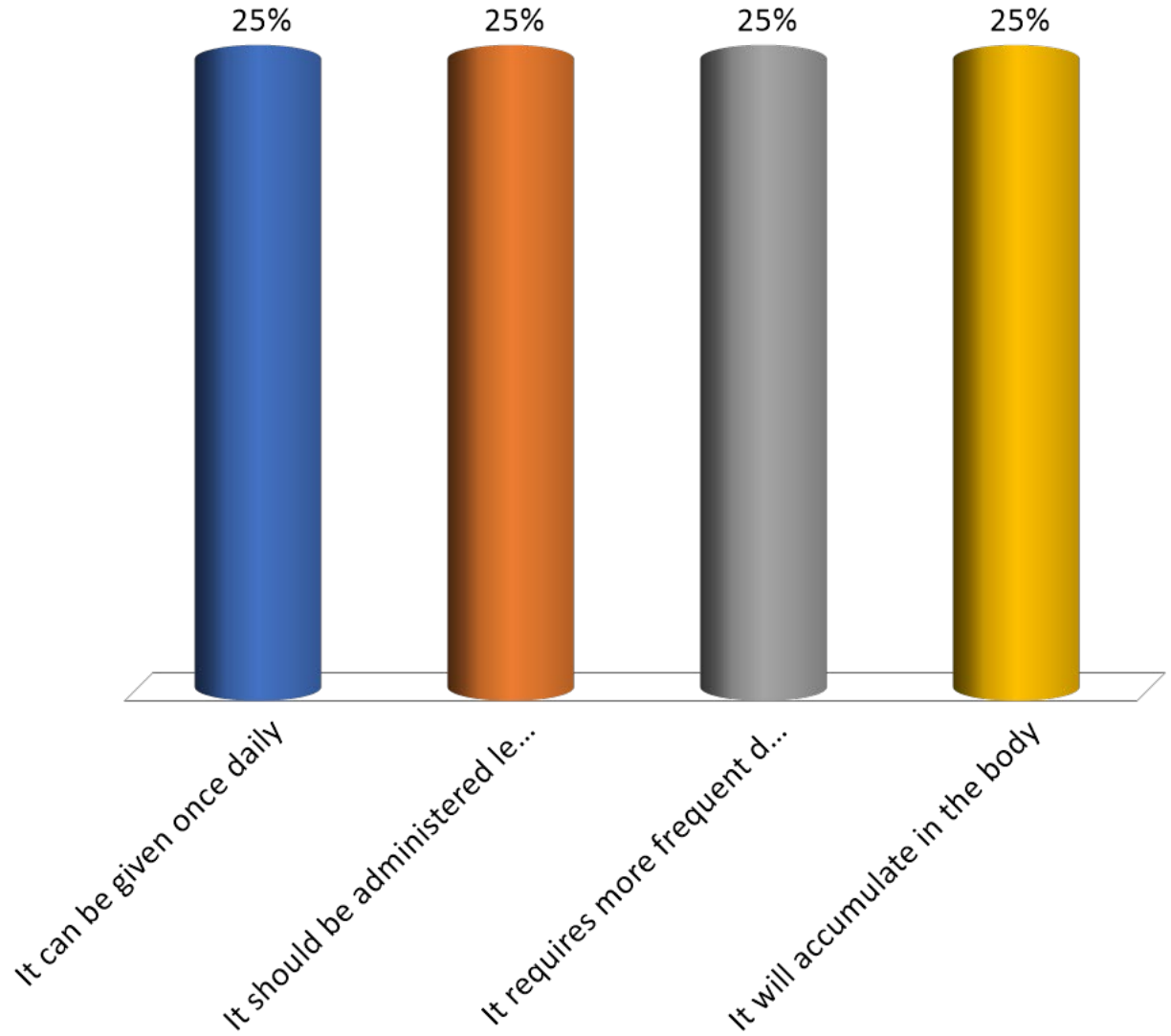
Q4: If a drug has a short half-life, what does that imply about its frequency of administration?

A. It can be given once daily

B. It should be administered less often

✓ C. It requires more frequent dosing

D. It will accumulate in the body



Q5: When it comes to excretion, which organ processes non-soluble molecules?

✔ A. Liver

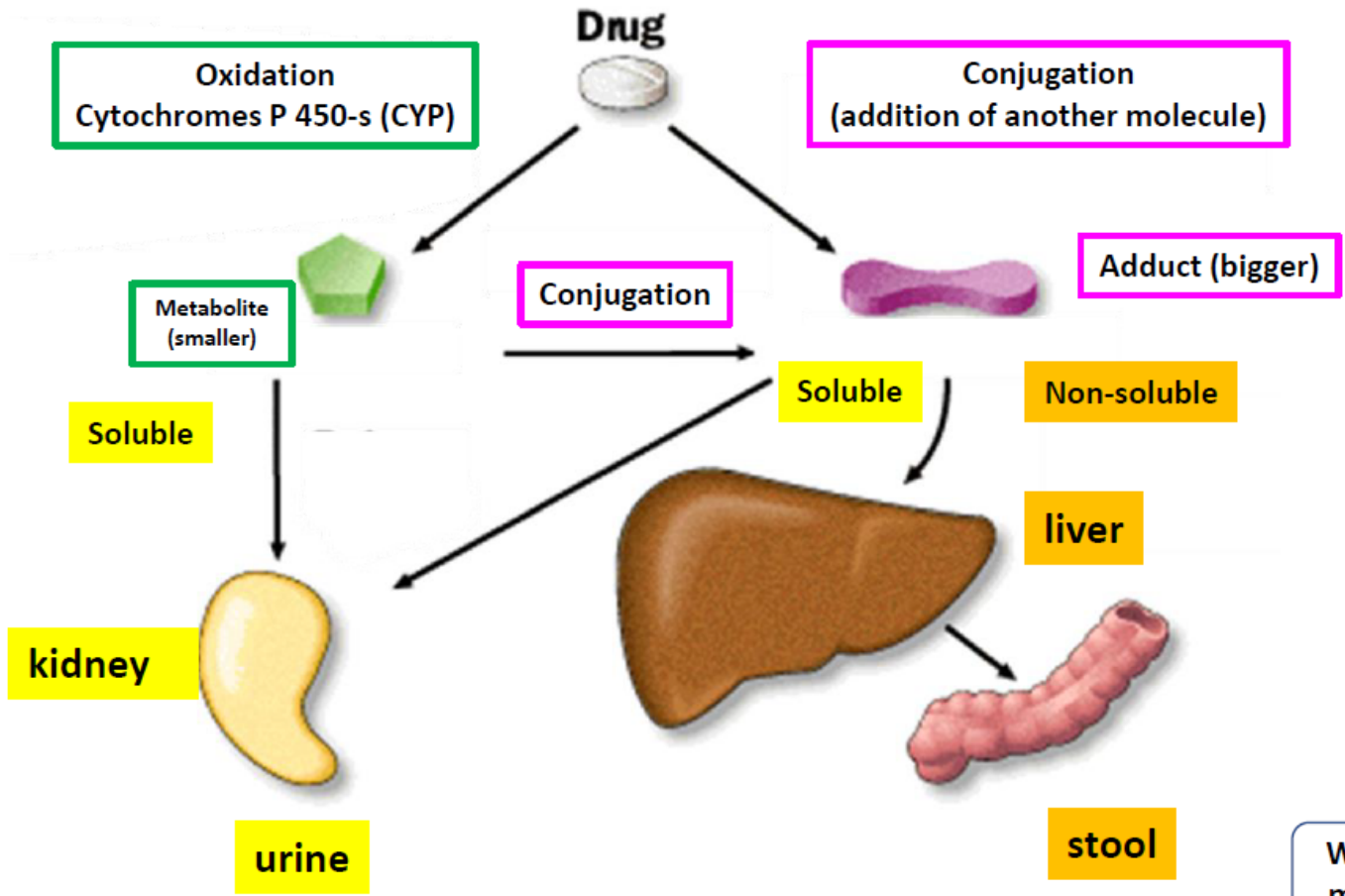
B. Kidneys

C. Colon

D. Spleen

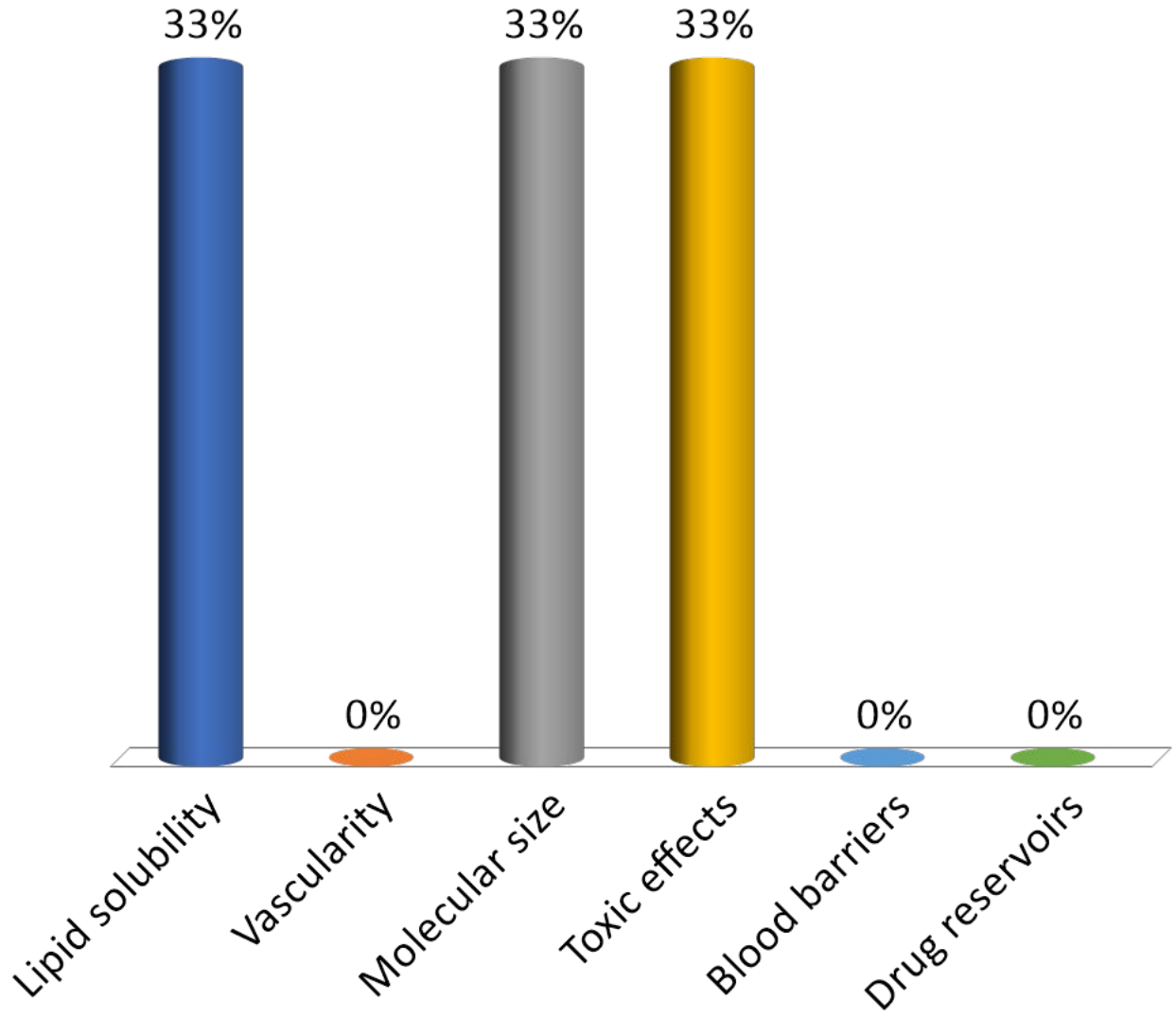
What is Excretion?

(aka how does the drug or what's left of it leave the body?



Q6: Which distribution-affecting factors are mainly related to the drug?

- ✓ A. Lipid solubility
- B. Vascularity
- ✓ C. Molecular size
- ✓ D. Toxic effects
- E. Blood barriers
- F. Drug reservoirs



What is Distribution?

(aka how does the drug travel into different locations of the body ?)

Factors Affecting Distribution of Drugs

Factors Related to Drug	Factors Related to Body
Lipid solubility	Vascularity
Molecular size	Transport Mechanisms
Degree of Ionization	Blood Barriers
Cellular binding	Placental Barriers
Duration of Action	Plasma Binding Proteins
Therapeutic effects	Free and Bound forms of Drugs
Toxic effects	Drug Interactions
	Disease States
	Drug Reservoirs
	Volume of Distribution

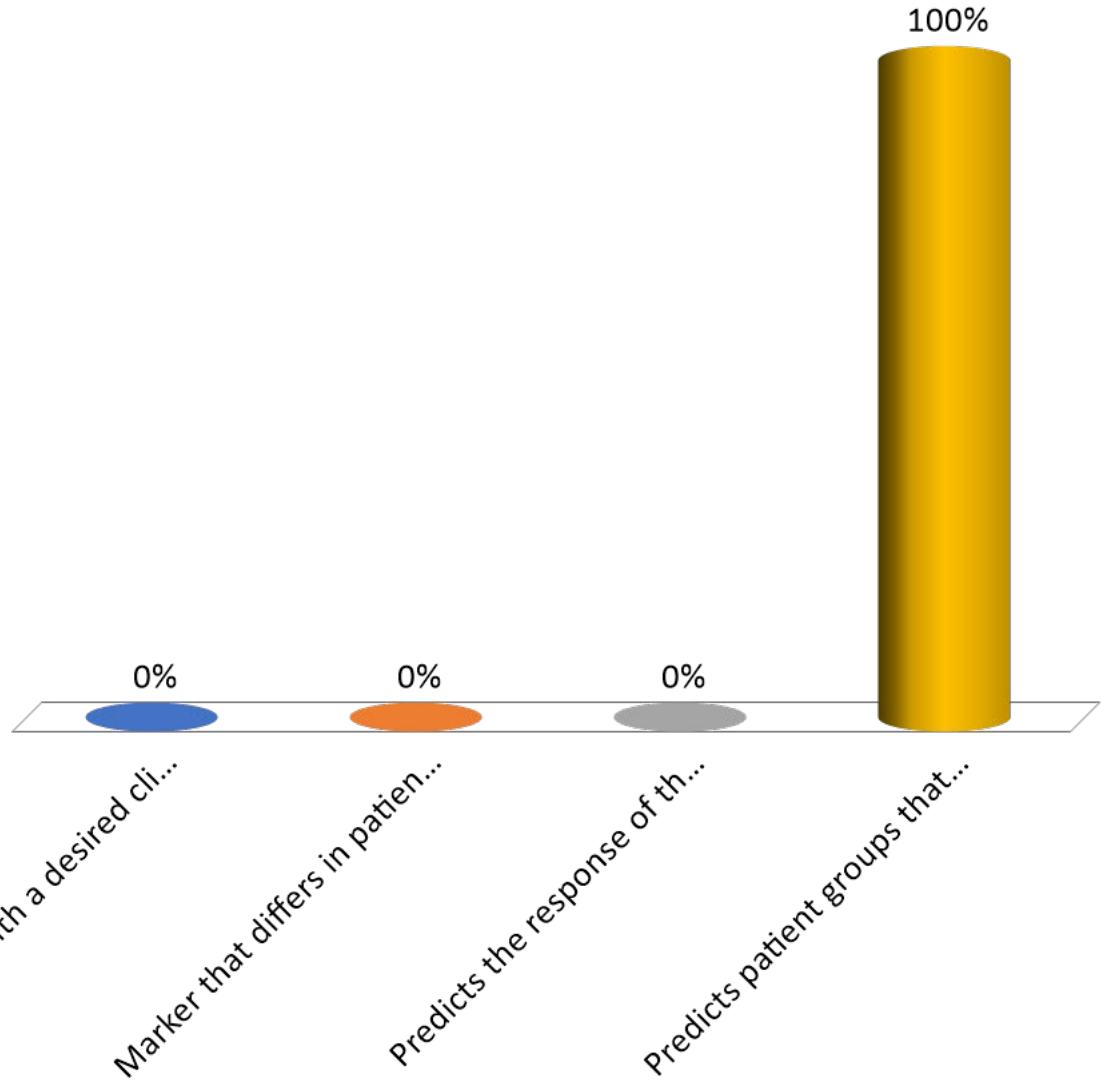
Q7: What is a stratification biomarker?

A. Correlates with a desired clinical outcome

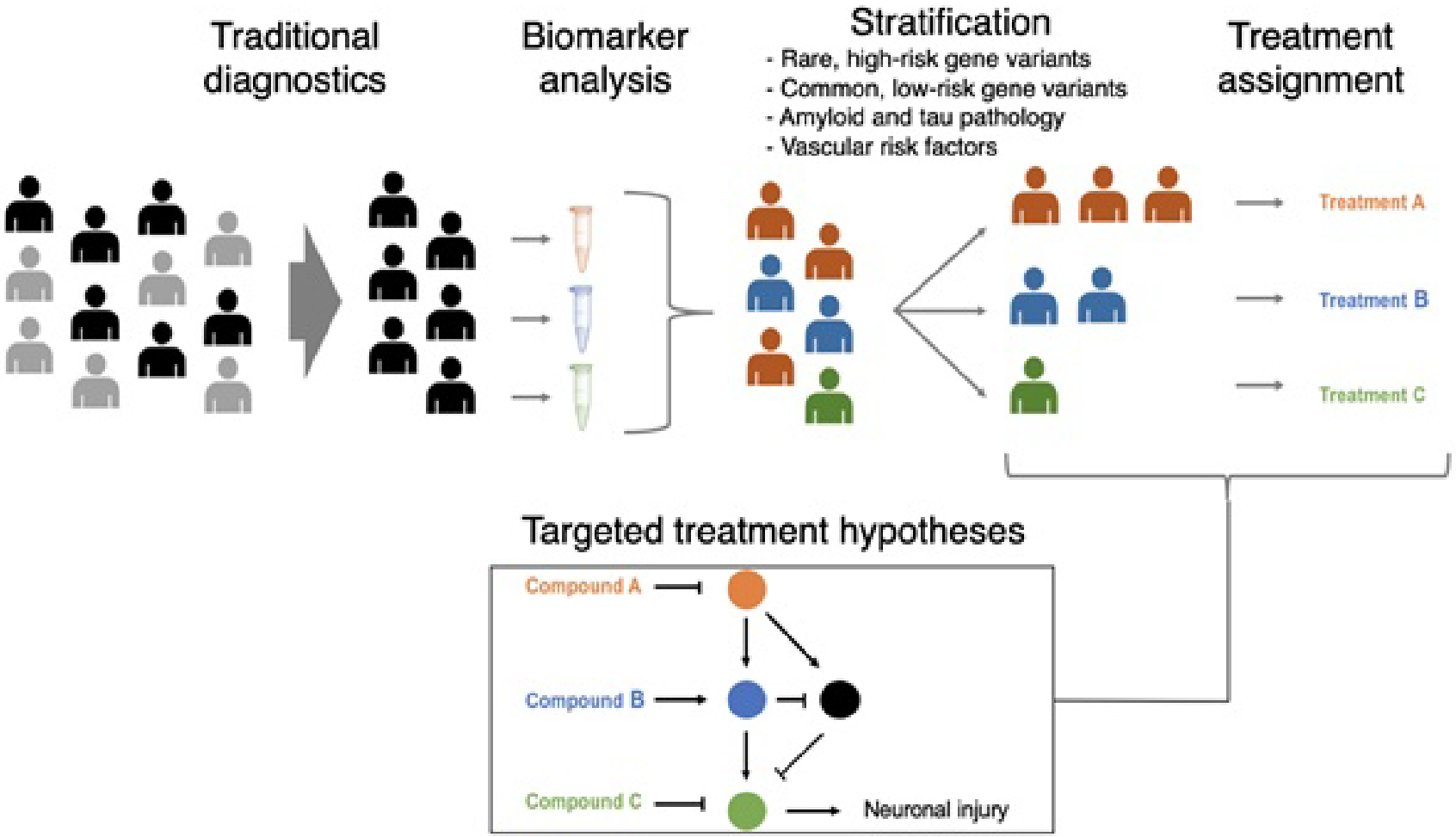
B. Marker that differs in patients depending on their ethnicity

C. Predicts the response of the patients to a particular treatment

✓ D. Predicts patient groups that will respond to a particular treatment



A Framework for Patient Stratification in Clinical Trials for Alzheimer's Disease



DOI:10.24966/AND-9608/100033

Q8: What is NOT one of the approval criteria?

A. Product is safe and effective

B. Patients' rights and well-being are protected

✓ C. Potential market price of the drug meets the affordability index

D. Product manufacturing follows strict regulations and are adequate to assure identity, purity, potency, and stability