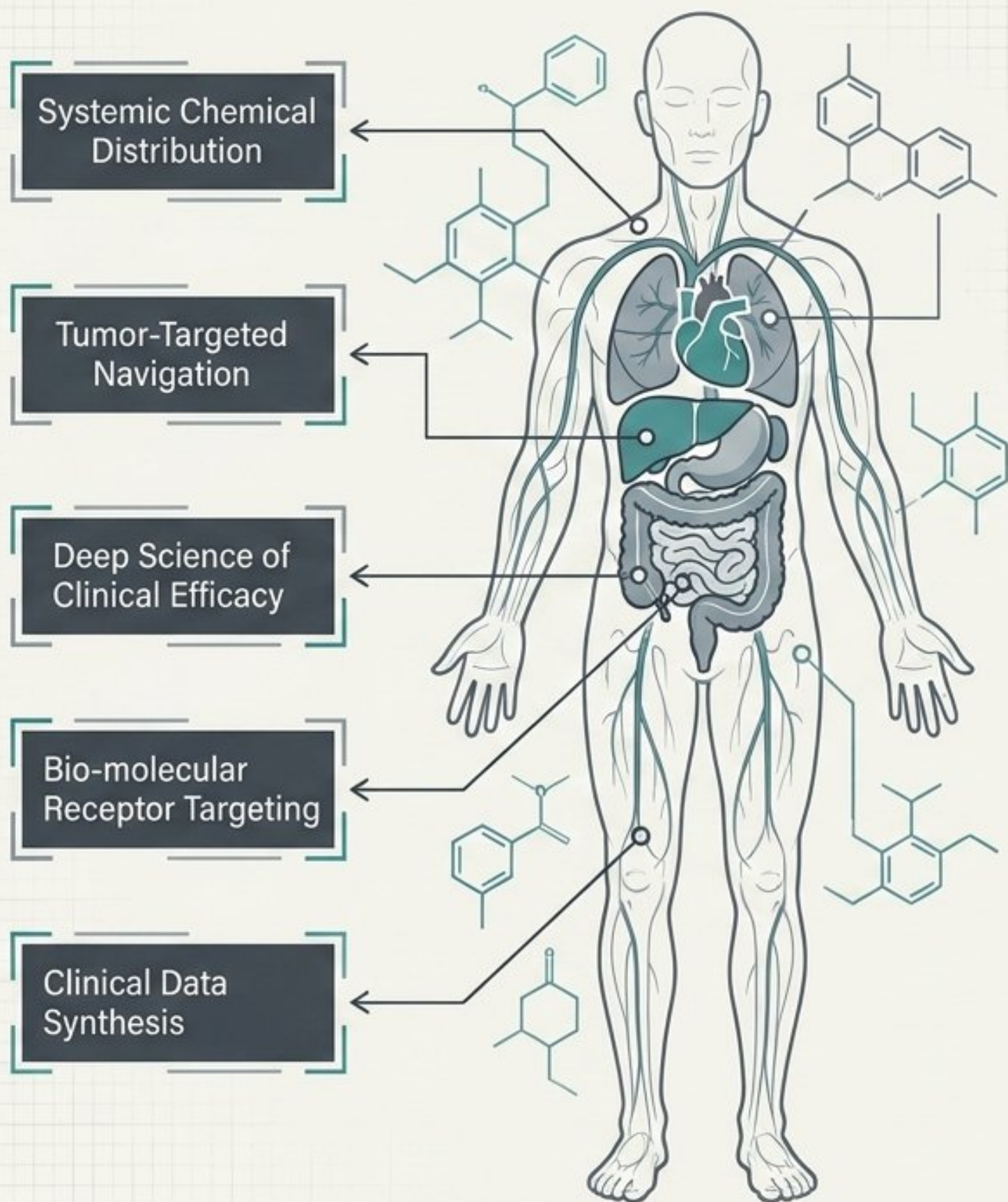


Drug Development Pathway of Anticancer Drugs

Shams Almiluk Mohammed





From Chemistry to Cure: The Science and Pharmacy of Oncology Drug Development.

A visual guide to how chemical design, targeted delivery, and clinical data unite to fight cancer.

Only 20% of drugs entering Phase 1 ever reach the market.

Phase 1: Discovery & Optimization

Finding the biological target and optimizing the chemical compound



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Phase 2: Preclinical (ADME & Tox)

Laboratory testing for absorption, distribution, metabolism, excretion, and toxicity



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Phase 3: Clinical Trials

Proving safety and preliminary efficacy in human patients across three sub-phases



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Phase 4: FDA Approval

Rigorous regulatory evaluation to guarantee safe, effective, and standardized use



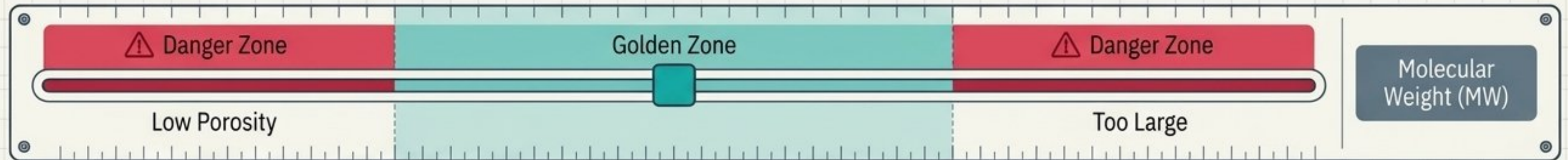
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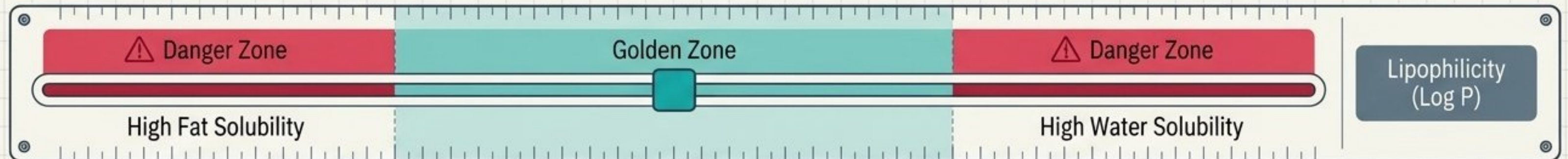
Market Entry

Phase 1 – Chemistry & The Golden Zone

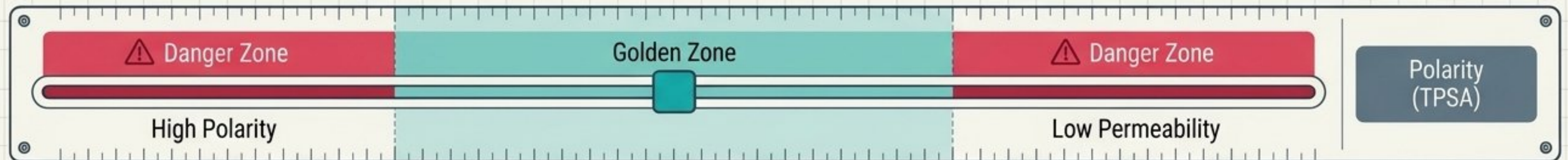
Cancer drugs must strike a precise physical balance: small enough to penetrate cells, yet complex enough to destroy tumors.



The optimal size threshold for cellular entry without getting trapped.



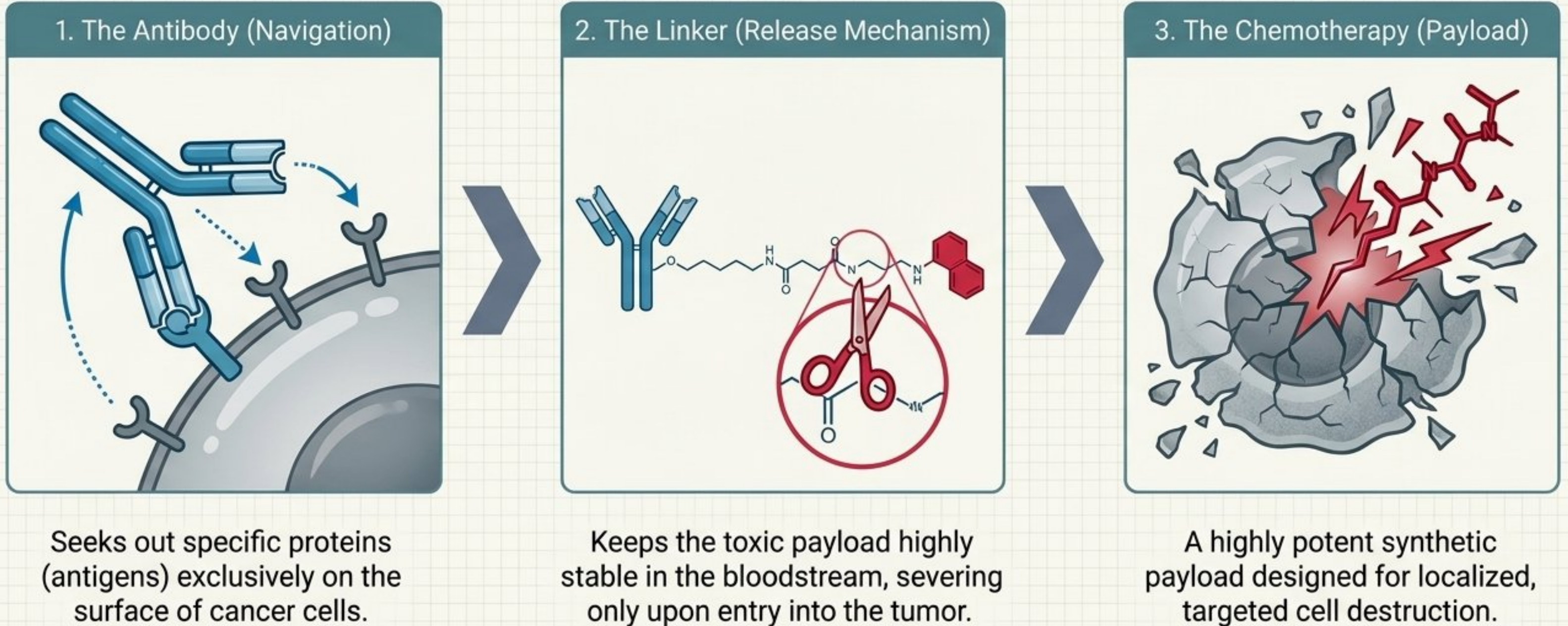
The delicate water/fat balance required to cross both the bloodstream and lipid membranes.



Dictates the molecule's ability to successfully breach biological cell walls.

Targeted Delivery: Antibody-Drug Conjugates (ADCs)

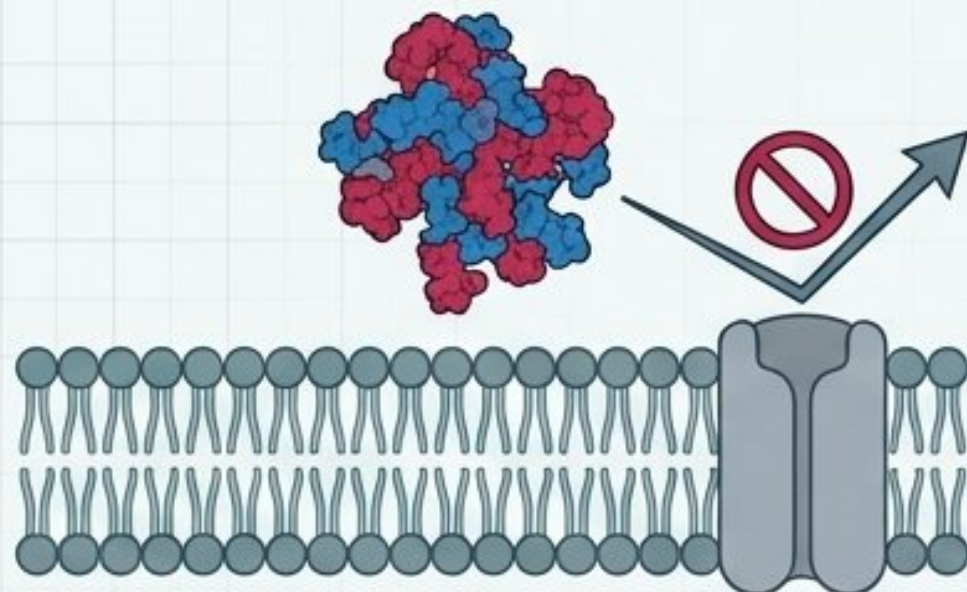
Combining the raw power of chemotherapy with the precision navigation of biology to spare healthy cells.



Cell Penetration: The CD36 Backdoor

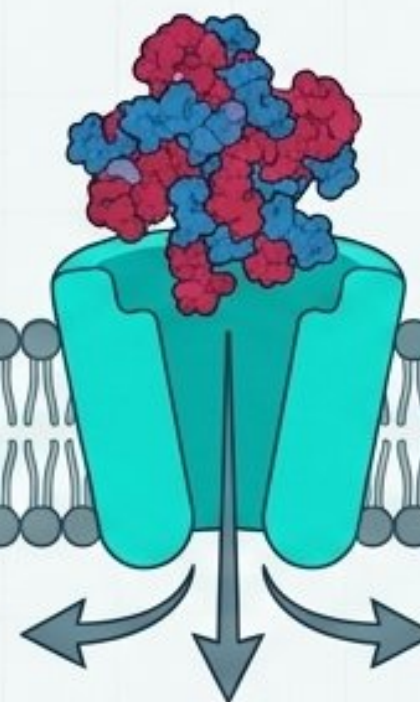
Bypassing normal cellular defenses to increase large-molecule drug uptake by 23x.

Standard Approach



Standard cellular defenses inherently block massive synthetic drug molecules from entering.

The CD36 Exploit

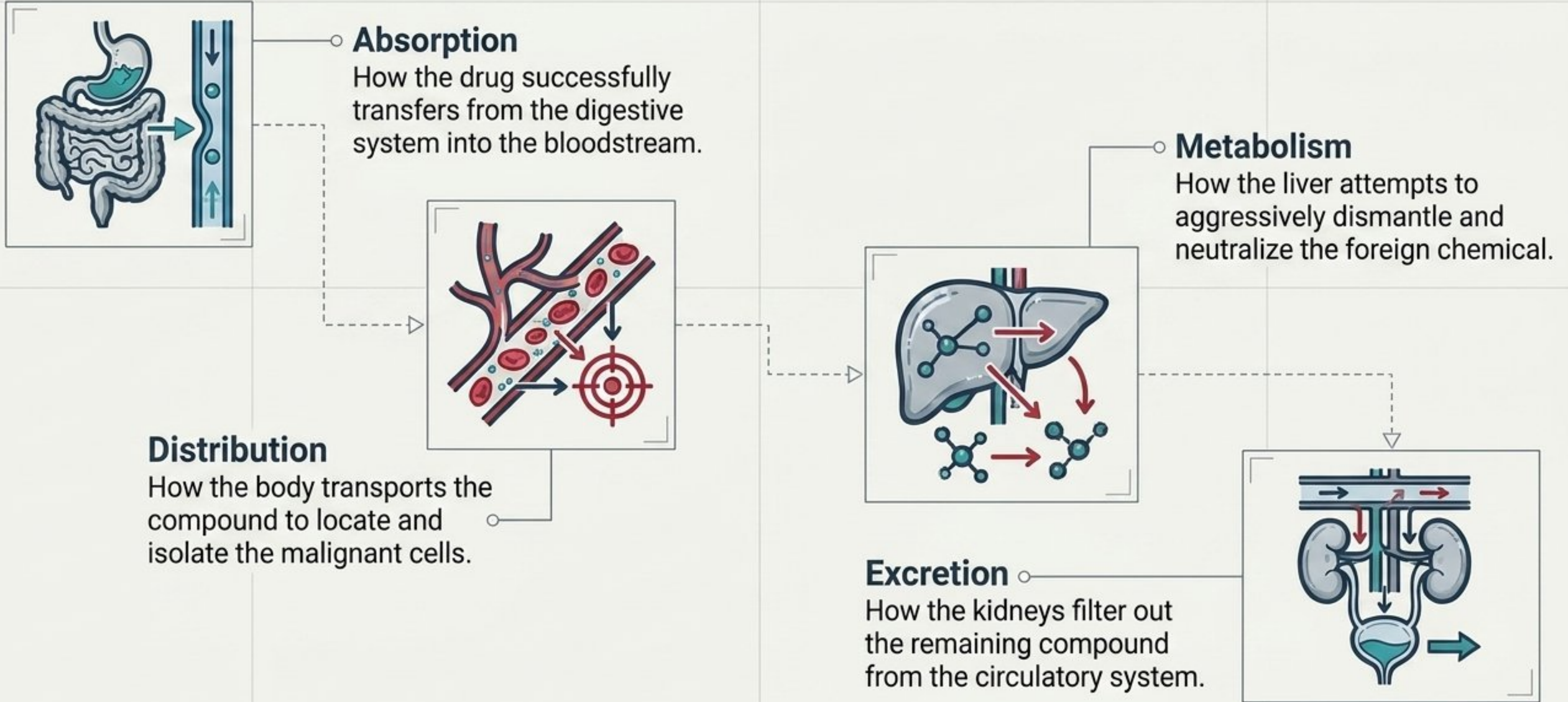


The CD36 receptor is utilized as a biological backdoor, allowing massive molecules to slip through undetected.

The Result: Once inside, the drug marks the cancer's own proteins, tricking the cell into destroying itself via the Ubiquitin-proteasome waste system.

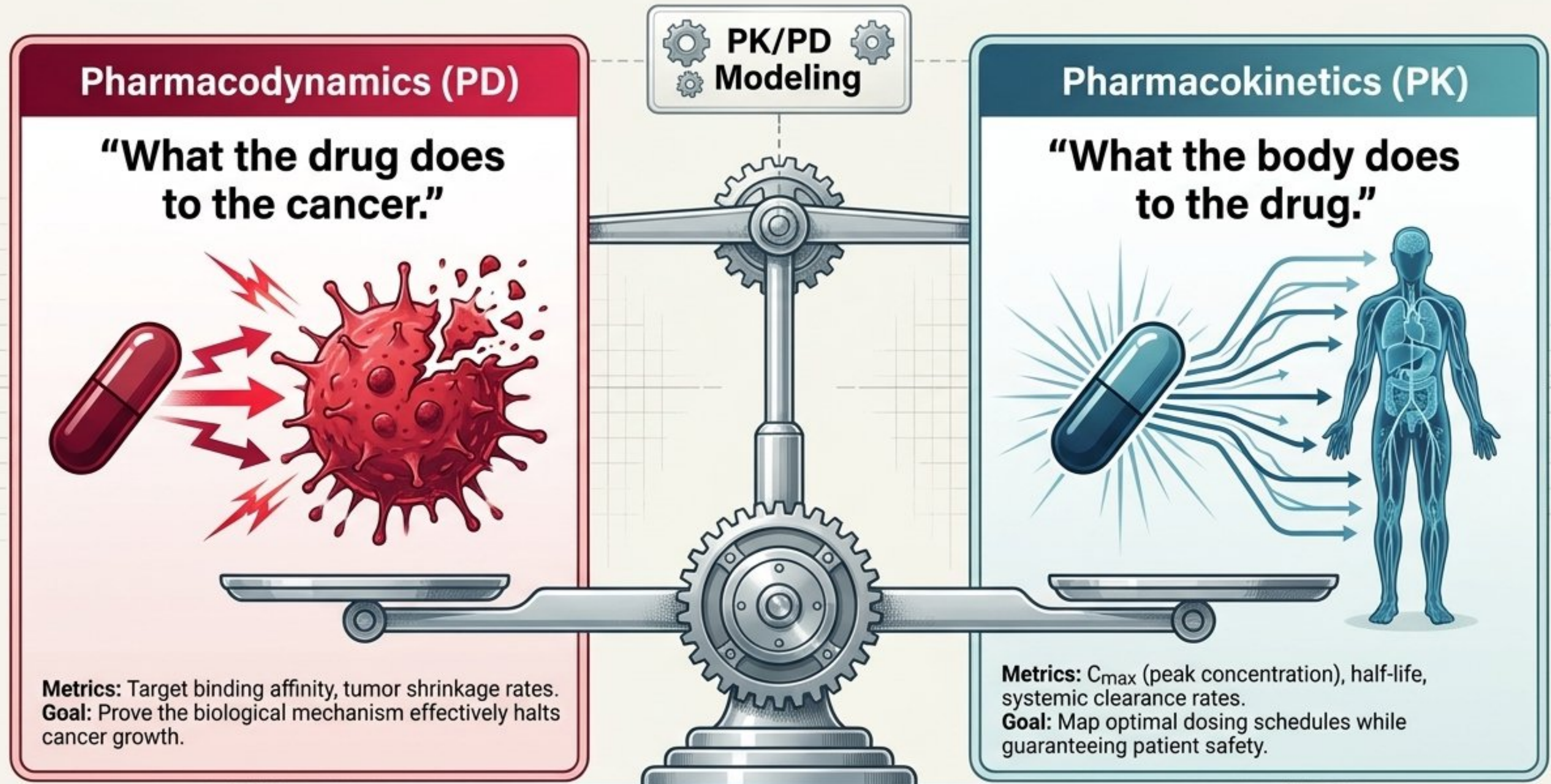
Phase 2 — The Preclinical ADME Journey

A chemical compound is only viable if it survives the human body's natural defense and filtration systems.



The Critical Balance: Pharmacodynamics (PD) vs. Pharmacokinetics (PK)

Distinguishing between what the drug does to the disease and what the body does to the drug.



Biomarkers: The Key to Patient Selection

Utilizing genetic fingerprints to match the right drug to the exact right patient.

The Concept

No two cancers are identical. Biomarkers are unique genetic or protein signatures specific to an individual patient's tumor.



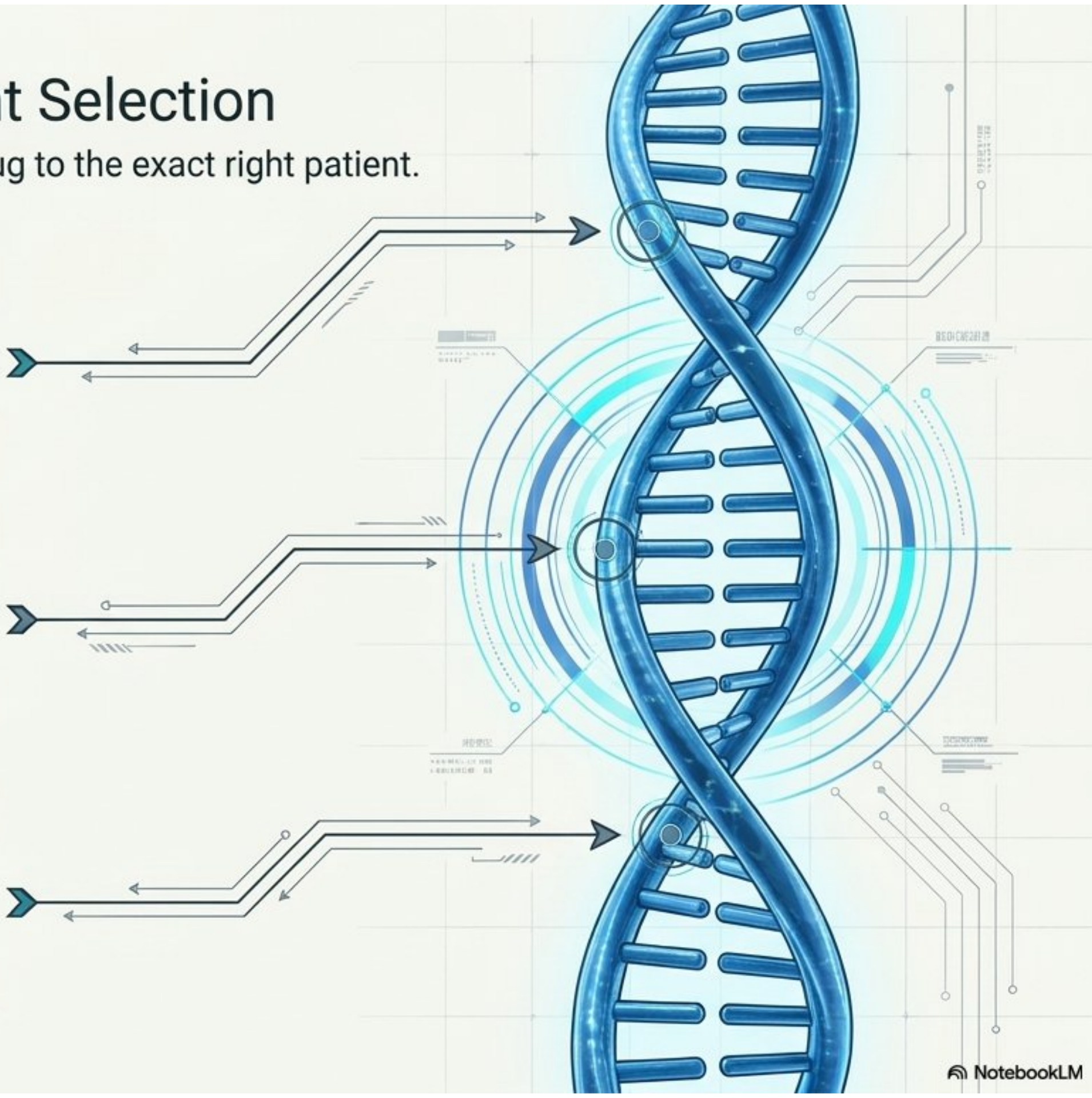
The Tools

Next-Generation Sequencing (NGS) is deployed to map the tumor's DNA and precisely identify these hidden biological targets.



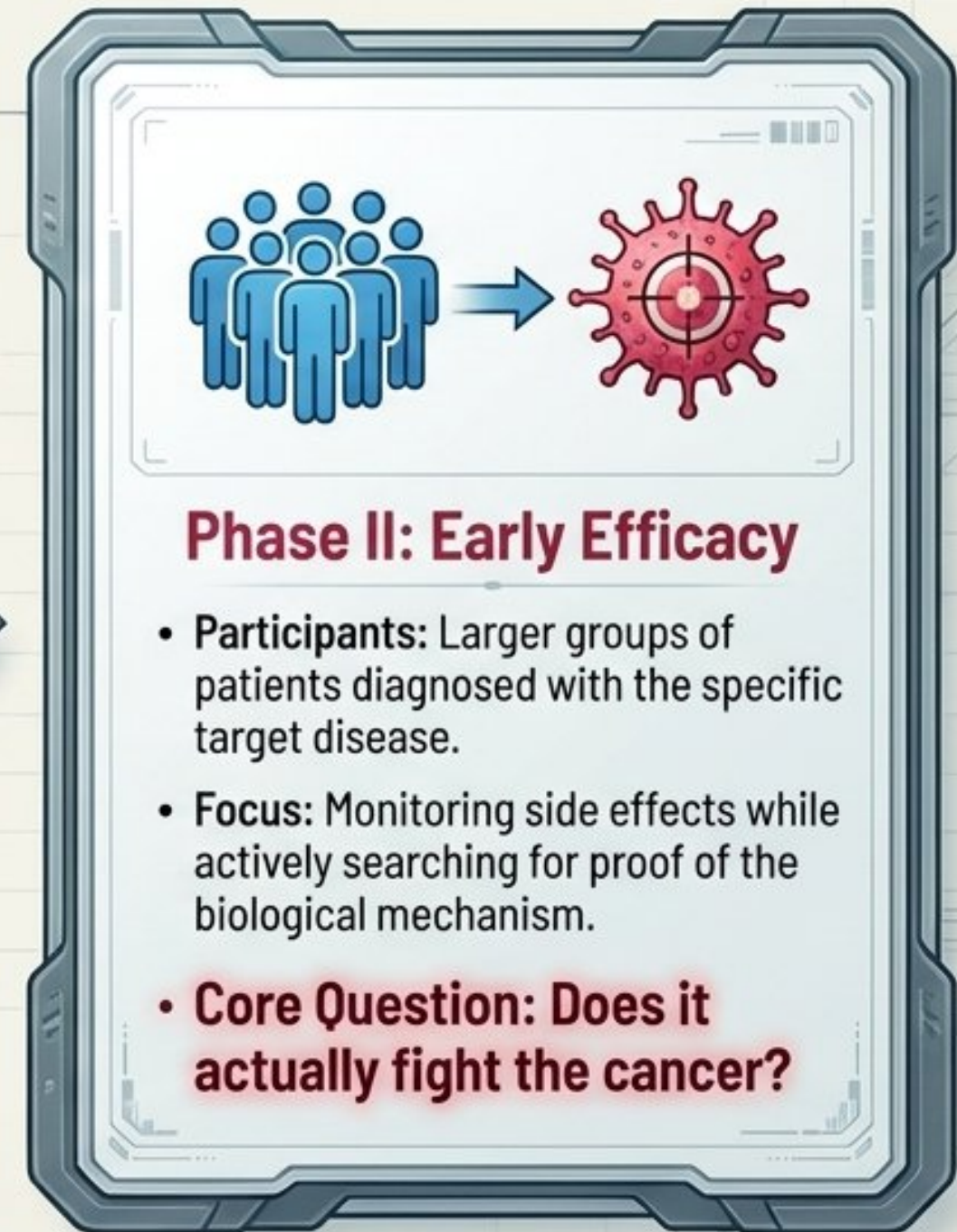
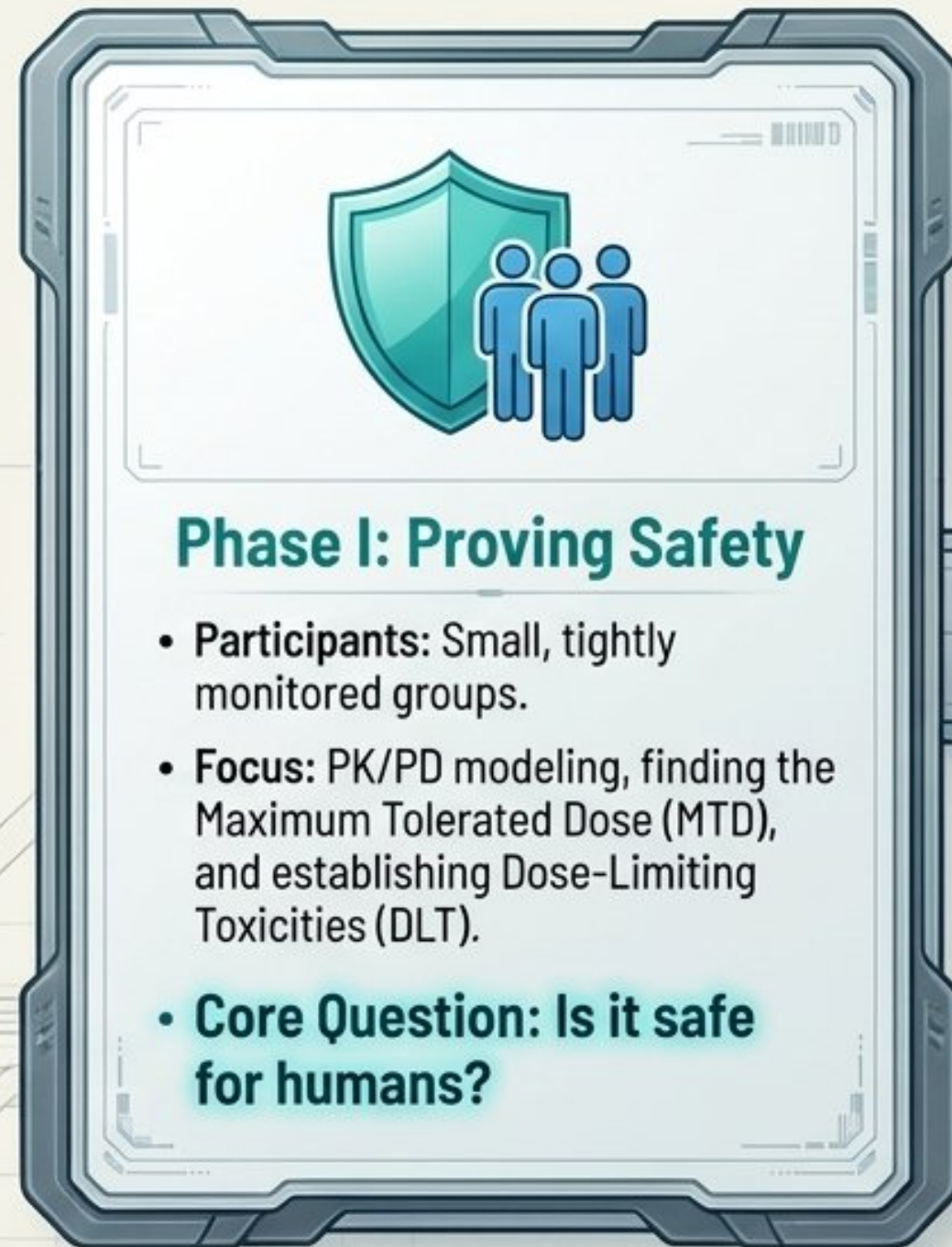
The Value

Enables true precision medicine. Proving target binding early eliminates guesswork and significantly shortens the overall drug development timeline.



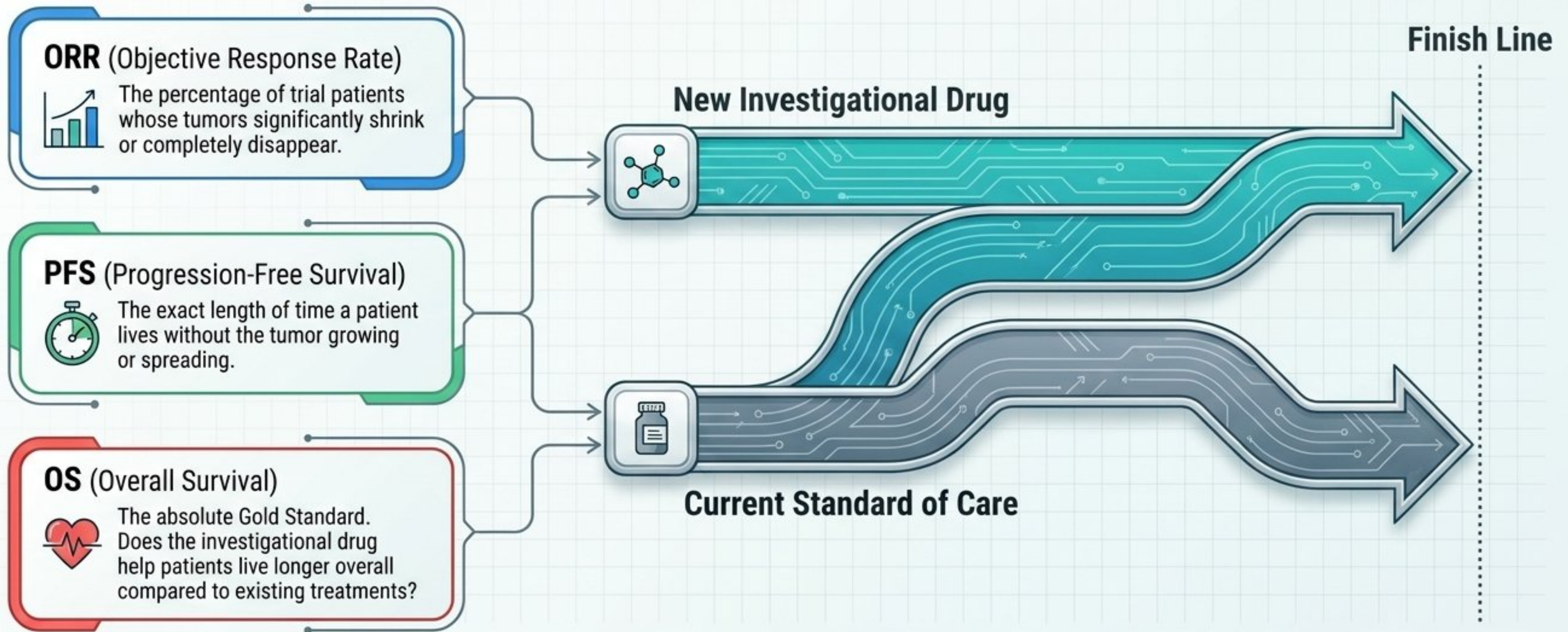
The Clinical Front: Phase I vs. Phase II

The definitive shift in clinical trial objectives from proving human safety to establishing biological efficacy.



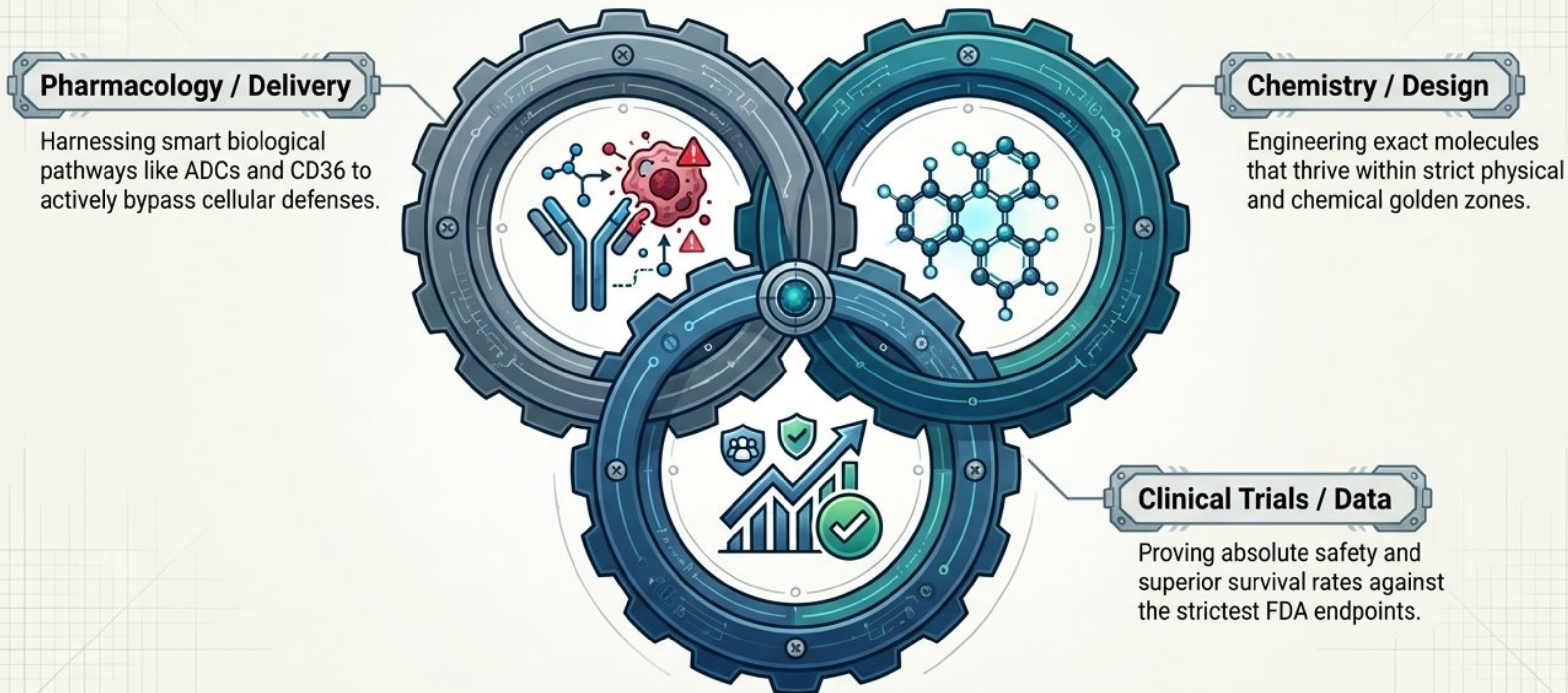
Phase III & FDA Endpoints: Proving the Cure

Approval requires more than efficacy; the new drug must definitively outperform the current standard.



The Integrated Oncology Ecosystem

True breakthroughs require perfect harmony between molecules, mechanisms, and metrics



Together, these disciplines turn molecular blueprints into life-saving realities.

Thank you

