

## The DYNAMIC Trial: Is it the Right Option for You?

It's no secret that conventional clinical trial design leaves ample room for improvement in oncology. Just 1 in 3 clinical trials for cancer drugs successfully advances from Phase II to Phase III. Among those, only about half make it to an approved drug.

# Given the urgency of cancer drug development, isn't there a way to be more efficient—and cost-effective, too?

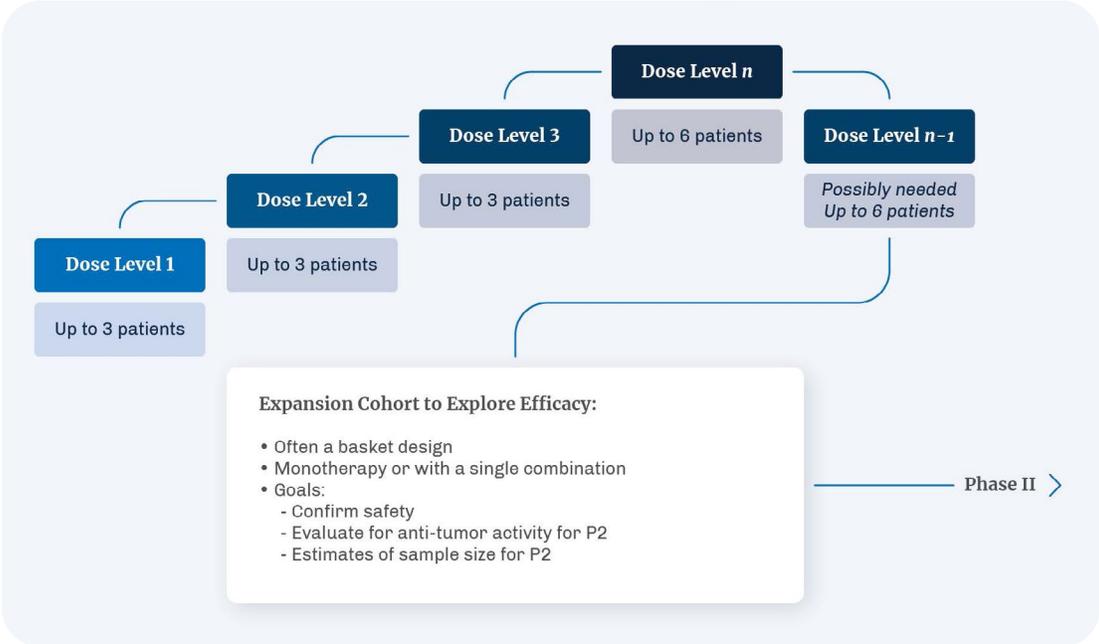
The FDA thinks so—as evidenced by a series of 2018 guidance documents that call for the need to modernize trial structure through adaptive design:

- Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics; Draft Guidance for Industry
- Master Protocols: Efficient Clinical Trial Design Strategies to Expedite Development of Oncology Drugs and Biologics; Draft Guidance for Industry
- Adaptive Designs for Clinical Trials of Drugs and Biologics; Draft Guidance for Industry

By using a change-as-you-go strategy that evolves as new data emerges, adaptive design saves time, money and resources. But how can you get there?

Enter TD2's **DYNAMIC Trial**, an adaptive approach to trial design that folds in more exploratory cohorts for faster insights earlier in the development process. In a standard design, those cohorts wouldn't come into play until Phase II. But in the DYNAMIC Trial, they're the very factors that inform Phase II design.

## Traditional Phase I Trial Design



## The DYNAMIC Trial Design

### Traditional Phase I Trial

Start with standard dose escalation and expansion



#### Add Multiple Expansion Cohorts:

- Protocol outlines "pre-planned" expansion cohort(s)
- Additional cohorts added in parallel or subsequently to:
  - Efficiently evaluate new pre-clinical data in patients
  - Explore new or combination treatment approaches (n=6)
- Trial objectives similar to Phase II studies
- Goals: Efficiently define registration pathway

Arms can progress into Phase II >

### The DYNAMIC Trial Multiple Expansion Cohort Example

- Arm 1:** Planned expansion cohort in CRC and HNSCC cancer
- Arm 2:** Expansion cohort from unexpected anti-tumor signal in pancreatic cancer
- Arm 3:** Subsequent cohort in combination with CPI for approved indications
- Arm 4:** While development in Phase 2, food effect, exploratory assessment on PK
- Arm n:** Add cohorts as new data becomes available

## Dynamic Trial Benefits:

### Cost Savings

It negates the need for multiple exploratory Phase II runs—reducing costs by as much as 75 percent.

**With the DYNAMIC Trial, sponsors can achieve in one multiple-arm trial what traditional models achieve in several independent studies.**

**75%** COST  
REDUCTION

### Fast Enrollment

With multiple recruiting arms, it accrues patients rapidly and more likely earlier in their treatment history.

### Reduced Trial Duration

It saves time—by as much as 18 to 24 months when compared to testing each patient population or combination design in separate Phase II studies.

**18-24** COST  
REDUCTION

### Open Master Protocol

Streamlines exploratory research by maintaining an open protocol designed to add a new arm to opportunistically test hypotheses or questions as new data become available.

### Strategic Clarity

It informs your best Phase II design based on real results obtained from multiple Phase I cohorts. You won't have to guess as to what the "best shot on goal" will be.

## Challenges of Dynamic Trial Design:

### Complexity

The trial protocol layout, database and operational plans must clearly allow for the adaptive approach.

### Vigilant Oversight

A larger number of patients exposed to your drug faster means you have to increase safety reviews.

### Intricate Execution

Diligent site management is essential to success.

### Combination Ambiguity

In the absence of randomization, response rate estimates when used in combination with approved drugs remain estimates against historical controls.

### 3 Signs You Should Consider the Dynamic Trial Design

The Dynamic Trial Design offers time and cost savings across-the-board, but it's not right for every investigation into every drug. If these three indicators apply to you, the benefits might outweigh the challenges for optimum results:

- 1.** You've got multiple hypotheses. If you have several clinical and scientific hypotheses that each rely on different testing scenarios, the Dynamic Trial Design is a great tool to filter out which of them are worth advancing—without wasting time and resources on multiple exploratory Phase IIs.
- 2.** You're looking to prove-up anecdotal evidence. If you see anecdotal evidence of activity from a Phase I, an added Dynamic Trial Design enables further investigation of that potential response—and you might find it wasn't just anecdotal after all.
- 3.** You're not sure where to go next. If you're not confident in the data and lack a clear signal on which direction to take your drug after its Phase I completion, a Dynamic Trial Design acts as an interim stepping stone—providing strategic guidance on where to go next.

### Ready to Get Started?

If you're looking for an expert team to guide your trial with efficiency in mind, we can help. As the creators of the Dynamic Trial Design, we provide start-to-finish support with trial strategy, design and execution for faster go-to-market potential.

[Contact us to get started today](#)