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The Missing Step Between Phase I and Phase II

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Too often, new drugs fail during development due to poor study design and inadequate knowledge about the performance of a new drug. A large part of these mistakes take place between Phase I and Phase II. That's why TD2 created the Dynamic Trial, an adaptive approach that adds exploratory cohorts for faster insights earlier in the development process.

What's the Dynamic Trial?

The DYNAMIC Trial features an add-as-you-go model, where expansion cohorts evolve as new data emerges. It appends exploratory cohorts to the Phase I trial to test various scenarios and clarify emerging questions about the drug's actual performance. Small patient cohorts can be explored to define the best go-forward strategy.

What's the Purpose?

The information gained in a Dynamic Trial study negates the need for exploratory Phase II trials, saving time and money. As a result, researchers can achieve in one trial what traditional models achieve in as many as four separate trials.

Is the Dynamic Trial for Me?

If you lack confidence in your drug's registration pathway and need more verification points before advancing to a definitive or pivotal Phase II—or you're considering several trial designs at once—you might want to consider this unique, adaptive trial design before moving straight to Phase II.

Is It FDA-Supported?

As a form of adaptive design, the Dynamic Trial model is not just supported by the FDA—it's recommended. Just a few months ago, for example, the agency released a guidance document that aims to modernize trials with this adaptive approach which TD2 has been performing for a decade.

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, TD2 provides start-to-finish support with trial strategy, design and execution for faster go-to-market potential.

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