



Clinical

# The Trends Behind Successful Cancer Treatments

Novel cancer drug research, development and new drug approvals are occurring at a staggering rate and the promise of significant clinical benefit for patients with cancer is breeding optimism among companies and scientists around the world. And for good reason.

**Seeing innovative and powerful forms of immunotherapy such as CAR T-cell therapy, anti-cancer vaccines, immunotherapies and new targeted small molecules are showing unprecedented response rates and bringing patients new hope and confidence.**

There is also the promise of exciting new anti-cancer approaches that are encouraging patients to participate in clinical trials, where there is an increased focus on early detection of clinical response, as well as the quantitation of exciting biomarkers of clinical activity that are being tracked in real time.

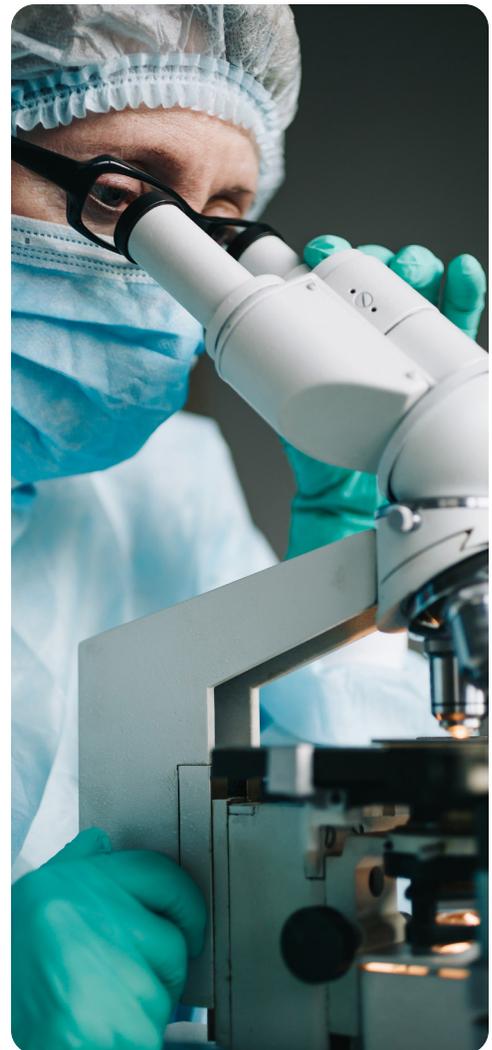
Despite the strides being made and constant innovation, pursuing a clinical trial remains timely, expensive, and risky. It is no secret that many cancer drugs may fail patients, but with a rigorous focus on the selection of patients most likely to obtain clinical benefit from a new medicine, companies are seeing evidence of early clinical activity for their drugs in well-defined patient populations. These more comprehensive understandings of how and when a new medicine may have clinical activity in a well characterized subpopulation of a type of cancer could lead to new drug approvals in these unique subpopulation contexts.

## **A Commitment to Evolve and Adapt**

Clinical trials should be initiated with a focus on success, and a commitment to evolve and have adaptive trial designs to respond rapidly to the early detection of response. There is a growing list of drug approval successes that companies can draw on for insights to determine the best opportunities for their particular drug and a trial design that can evolve as needed to achieve the desired outcome. It may sound counterintuitive, but the smartest studies gain efficiencies as they evolve and adapt. Poorly designed studies have the opposite effect.

## **Start with the End in Mind**

When designing trials, it is also important to plan for clinical success and define very early how the drug will be approved. It is widely known that if a drug can potentially treat a cancer that lacks existing approved treatments, the opportunity to utilize FDA-established mechanisms to accelerate the review and approval of your new medicines increases. For this reason, five new drugs received FDA approval towards the end of 2019 on significantly reduced timelines. In line with the commitment to evolve and focus initial efforts on the end game, it is also wise to follow an adaptive approach that adds exploratory cohorts for faster insights earlier in the development process to save time and money in the long run.





## Case Study

### The Dynamic Trial

**When TD2 was approached by a client to design a unique trial, they applied their Dynamic Trial model. The Dynamic Trial employs a change-as-you-go strategy that evolves as new data emerges, and features an adaptive design that saves time, money and resources.**

A multi-arm trial was designed leveraging both expert knowledge in oncology drug development as well as data from preclinical models performed by TD2 testing those clinical hypotheses. During the course of the trial the translational team quickly uncovered a unique regulatory development opportunity that could be rapidly explored within the open trial. To validate the patient response seen in the trial, an arm was added within weeks by a simple amendment to explore that specific patient population and further validate the signal. The Dynamic Trial takes some of the guesswork out of planning your Phase II trial strategy and allows you to explore multiple clinical settings and choose the path forward that gives your promising oncology medicine the greatest chance of success.

## Find the Right Partner

Working with a dedicated and specialized oncology Contract Research Organization (CRO) like TD2 to oversee trial design start to finish can be a significant advantage. TD2 has preclinical, regulatory and clinical services in house and a strong track record and reputation for developing a well-defined clinical and regulatory strategy featuring their industry-leading Dynamic Trial.

[Contact us to get started today >](#)