TD2 Precision Oncology

Many Drugs Don’t Move Past Phase I. Will Yours?

A high percentage of cancer drugs may never advance beyond the first phase. How can you boost the chances that yours will beat the odds and have a better chance of success? It starts with a sound preclinical plan comprising three essential components. Do it right and do it early and you might see your drug cross the finish line faster (and cheaper) than you ever thought possible.

3 Essential Parts of Any Preclinical Plan

The best programs start with the end in mind: By identifying a drug's clinical and regulatory strategy, it can save time and resources as the drug program progresses. And that means fail-proofing early designs with these three essential components:

1. **Apply Lessons Learned:** Protect your compound from pitfalls by applying lessons learned from existing late-stage research. Identify opportunities for your drug to succeed where others have failed by putting in due diligence on the front-end, even if doing so makes for a slow start.

2. **Employ PK/PD Analytics:** Make use of pharmacokinetic and pharmacodynamic insights at the onset—and adapt them as new information arises at each phase of development. Doing so can help boost a cancer drug's likelihood of success.

    - **PK analytics** identify how long a drug stays in plasma/serum, tumors and other tissues of interest.

    - **PD markers** provide key insights into a drug's mechanism and can reveal early signs of activity—giving you confidence that the drug is working.

3. **Turn to Models (With Diligence):** Early employment of diligently selected, well-characterized tumor models is important. Ensure your selections are validated in relevant clinical settings and that they align with your drug's mechanism of action.

After all, if you show efficacy in the clinical trial faster, FDA approval is more likely to follow not long after.

Find Biomarkers, Find Success

Even though oncology drugs have low success rates when it comes to progressing from Phase I to Phase II, studies have shown that trials using biomarkers for patient stratification are better poised for success. Planning your preclinical programs to include a thorough evaluation of potential biomarkers for patient stratification and increased anticancer response is an essential part of the TD2 approach.

Applications to Rare Cancers

While a strong preclinical strategy benefits all drug development programs, those working in the realm of rare cancers have much to gain. If you can prove early on that your drug can safely serve patient populations for whom current therapies don't work, the FDA is more likely to expedite and grant approval.

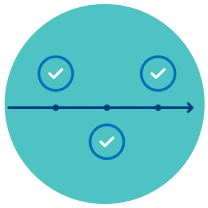
A groundswell of opportunity lies in drugs for the rarest cancers—such as pontine glioma, adenoid cystic carcinoma and thymoma. If the preclinical phase yields upfront proof that the drug can succeed, its prospects to advance past Phase 1 look good.

The catch? You need a well-planned preclinical strategy to get there—with the right models.

TD2: The Premiere Partner for Preclinical Studies

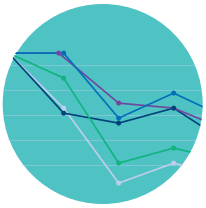
TD2 is in a unique position to help clients get their drugs past Phase 1 and closer to FDA approval:

We commit 100 percent of our resources exclusively toward oncology drug development programs.



We're with you at every step of the process—from the preclinical and clinical phases to regulatory review (and beyond).

We have more than 400 oncology models, inclusive of syngeneic models for immuneoncology and cellular therapy models for hematologic and solid tumor cancers.



We provide relevant, adaptable PK/PD analytics from start to finish.

Ready to Get Started?

If you're looking for a full-service team to help your drug succeed, let us prove your concept earlier in the process and increase your chances for a timely and cost-effective FDA approval.

Contact us to get started today

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Contact

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