



Your Partner in Oncology Drug Development

Managing the risks of developing new cancer drugs

The odds are against you when playing roulette. Ask Blaise Pascal, mathematician and inventor of roulette in 1655. Every player hopes to win but most lose. In developing new cancer drugs, the odds are against you too. Most drugs fail. However, unlike roulette, you can manage the risks. But what are those risks?

One example may clarify the risks in oncology drug development. Take a new drug against high blood pressure. Preclinical targets, mode of action, pharmacokinetics in healthy volunteers are usually clearly defined in early stage development. The clinical path is straight forward with target patients and clinical endpoints well known. The burden of proof is in the numbers showing superiority in a phase III trial with up to 10'000 patients. Now, take a new cancer drug. The preclinical targets, mode of action and pharmacokinetics are usually less well defined due to the heterogeneity of cancers. Even if they are, animal data poorly predict human outcome. How about choosing the right subset of target patients out of the 200 tumor types? And what about the multiple lines of therapy and potential drug combinations? Getting dizzy? The clinical path forward is risky facing many uncertainties and complexities. The burden of proof in early stage clinical development is translating preclinical data into feasible clinical studies to get proof of concept.

To manage your oncology drug development risks consider to:

1. Make science serving not dominating your clinical operations – science facilitates
2. Use the input from clinical rather than scientific experts in clinical planning – do not be afraid to look for help
3. Do not solely rely only on the input from opinion leaders to design your clinical program but involve them – you decide
4. Build a clinical development plan based on facts not assumptions – be realistic
5. Build a clinical plan that balances science, clinical operations and business – build a commercial label that sells
6. Focus relentlessly on getting proof of concept – show me a cancer drug that works
7. Keep operations simple in a highly complex science field – do not overcomplicate
8. Let an expert team run the studies – expect the unexpected and resolve problems fast
9. Work with a principle investigator that believes in your development plan and stick to the plan – no room for distractions
10. Double check details to ensure your protocol is practical – avoid amendments
11. Focus to achieve LPO (last patient out) more than FPI (first patient in) – end results count

Early stage clinical development can make or break your new cancer drug. Pay a good deal of attention to it. Faites vos jeux!