

DEAL GURU

- Few biotech companies know the pitfalls of contracting with contract research organizations. Here's a crash-course on how to survive it!

Small biotech companies with limited in-house staff rely heavily on outsourcing. Consequently, clinical trials - and in many cases thereby the destiny of the company - are handed over to vendors. When problems emerge, big pharma can pull business back in house. Small biotechs don't share this luxury, and cannot cope internally with the unfinished tasks or mobilize sufficient resources to relocate tasks to alternative CROs.

"Believing the contract will rescue you in case of issues with your CRO may be the worst mistake you can make. Unless - you took the time to seriously consider how to compose and execute the contract spending hours, days, or even months on a contract that you hope will never have to come into action"

This is a major challenge to small biotechs which do not have their own outsourcing or procurement groups, and whose limited staff is working hard to keep all plates running.

Understanding the DNA of the Contracting Parties
CROs and biotechs have different focus, and their employees are measured on different deliverables. Biotechs' goal is first and foremost to quickly capitalize drug candidates. Failure in this respect may be lethal. CROs need to make a profit from their services or they will not remain long in business. The common goal for both companies is to complete successful trials. However, delayed timelines increase the gain for CROs - and the pain for biotechs.

Contracting - Time vs. Risk

Biotech companies are typically tempted to rush ahead and 'figure out the details later' - an approach which rarely pays off. Not uncommonly, CROs start performing services under "Letters of Intent" ("LoI") before a contract is properly negotiated. The window of opportunity to move risks to the CRO is often closed unless the budget is increased, if details are only negotiated after execution of LoIs. This approach cannot be recommended since it leaves sponsor on an uneven, slippery negotiation platform, where the de facto award of the contract to the CRO sets the scene.

The Devil is in the Detail

The closing of a detailed service agreement and statements of work prior to services being rendered is a necessity if biotech is to keep the upper hand in the execution of the trial.

Hence, CRO proposals should be procured on basis of biotech drafted tenders and not on basis of individual CRO offers, which are seldom comparable. By carefully considering and communicating the required CRO services the risk of emerging out-of-scope activities triggering expensive change orders is mitigated. By doing your homework before CRO selection, the number of headaches and budget constraining conflicts are likely to be reduced.

Delegation

Even if the trial is fully outsourced to a CRO, sponsors always retain the ultimate responsibility for the quality and validity of trial data. However, sponsor should require the CRO to remedy defaults relating to duties and functions assigned in writing to the CRO. The trial activities to be assumed, performed, checked and/or supervised by CRO must therefore be carefully specified in writing. The risks of additional costs or quality problems emerging as result of unforeseen activities or conflicts are minimized if roles and responsibilities are clearly defined.

Take Control and Contract Directly

As sponsor you need to take control of your trial. Specify monitoring and audit rights and consider proactively the consequences of e.g. changes in CRO staff, training issues, quality procedures and study delay provisions.

A fairly common pitfall is to allow the CRO to be the contracting party with investigators, sites and sub-contractors. However, your business with sites and other vendors should not be compromised or put at risk if your business with the CRO comes to a premature end.

To secure a relatively smooth and uninterrupted continuation of the trial you should contract directly with third parties (e.g. vendors, investigators and sites) or ensure that the CRO signs as sponsor representative, and not in its own right.

Remedies

The CRO services comprise generation of valid data required for registration purposes.

Non-achievement of this goal for reasons due to the CRO should imply that the CRO loses compensation entitlements and assume liability preferably on a liquidated damage basis, as concrete losses are difficult to prove. The project is not safeguarded by such measures, but at least the biotech company may be in a position to have a second go.

Protect Ownership

Proper protection of intellectual property rights, documents and data must be a top priority. Ownership of e.g. research data and technologies developed during the trial must be clearly outlined in all contracts.

Insolvency

CROs may be unable to deliver for financial reasons. Often the contracts define such situation as breach entitling sponsor to terminate. However, in a number of jurisdictions such clause is rendered void allowing the estate administrator to assign the contract to another CRO or otherwise commercialize the contract to the benefit of creditors. To mitigate the insolvency, sponsor must at all times retain access to documents and data and on a current basis pursue its IP rights.

Build a Way Out

Despite time invested in profound CRO selection and mapping of the road ahead, things may not work out.

The financial consequences of termination, unrelated to breach, should be defined and agreed beforehand. Remember that the CRO should only be entitled to terminate in case of breach by sponsor.

Termination provisions are not necessarily the answer to even major problems, as switching CRO in the middle of the trial may well take sponsor out of the frying pan, but into the fire.

Less is Not More

In contract terms - less is not more.

To survive you will need to:

- Be comprehensive and detailed
- Allocate time and resources for contracting
- Assess vendors thoroughly
- Define your requirements; quality, time, money, milestones, liabilities, remedies

- Protect your IP ownership
- Ensure a way out of the contract
- Stay in control!




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