CRO Charité Research Organisation

scientifically driven

Turning Theory Into Practice: Successful Collaboration Between Pharma and AROs

Interactive Session

Use of "Fair Market Value" Pricing

Is this really "fair"?

The Sponsor intends to select an ARO to support its new Phase Ib study in T2D patients. The ARO plans to run the study in a dedicated clinical research facility and has presented a budget for doing that. The Sponsor policy is that the clinical budget for the study must adhere to "fair market value" pricing. Upon checking the budget, it appears that the many of the individual items and the overall budget are significantly above "fair market value". The ARO argues "fair market value" isn't really an appropriate tool to judge the budget by. It also argues it needs to commit to hiring a new team member specifically to perform some of the key assessments and this staff cost needs to be covered.

1. Is it ok to consider covering the cost of a new staff member as opposed to just paying for specific assessments they perform?
2. What possible options exist to bridge the gap and meet the objectives of both parties?

Which Type of Contract is Best Fit – Site or CRO Services contract?

Is it not possible to have one that covers both investigational site type work and CRO services?

The Sponsor intends to select an ARO to support a Phase I study combining dosing in HVs with dosing in UC patients. The preferred ARO plans to conduct the HV part in a dedicated facility and support the UC part by working with a clinic. The ARO will also provide some support services, such as support for protocol development, local ethics submission and even Data Management. The ARO argues that all of this work can be covered by a single contract that covers clinical conduct (investigational site work) and CRO like services (submissions, DM, etc). The Sponsor is not used this type of arrangement and feels that the work should be split between an "Investigator Agreement" and a "CRO Services" contract. The ARO thinks this is unnecessarily complex.

1. What are the likely thought processes and reasons for using two contracts?
2. What could be done to allow a single contract to be used?

Handling the Consequences of Promises Made to KOLs

Dealing with delicate situations

Your company has just licensed in a compound. The team behind the original development of the compound have a close relationship with a KOL who is considered vital to the project. The compound is about to enter a Phase II trial. The original developer has already agreed with the KOL that, not only will he serve as PI for the study, but he can conduct exploratory biomarker work as part of the trial. The problem is that this exploratory biomarker work will involve multiple partners on the KOL side. His site is already managed by an ARO and the biomarker work is set to involve at least 8 other partners, including other university hospital departments and an external commercial local laboratory. It is not clear how this exploratory biomarker work can best be contracted to ensure it can go ahead as promised while maintaining sponsor rights and appropriate compliance.

1. What are likely to be the key issues and contract terms at stake here?
2. How could this work be contracted in a streamlined fashion across so many individual contributors?

Charité Research Organisation GmbH

Charitéplatz 1
10117 Berlin, Germany

enquiries@charite-research.org
www.charite-research.org