PCMG ARO GUIDELINES

FREQUENTLY ASKED QUESTIONS

1. Why should I work with an ARO instead of a CRO?
There are a variety of reasons why pharma and biotech companies choose to partner with AROs, but it usually revolves around access to a key element of the clinical trial or programme. This may be scientific expertise (especially related to a new therapeutic area), access to patient populations, data, technology or specific capabilities. You may also wish to leverage the reputation of key opinion leaders or utilise their independence for certain key roles within the drug's development. Increasingly AROs are being seen as a strategic partner by Pharma, especially in cardiology, immunology/inflammation and oncology therapy areas where there is an increased focus on accessing targeted patient populations, building efficiencies in the trial design and reducing recruitment costs.
2. I've just been told to put a contract in place with an ARO. Where do I start?
First of all, you might want to ensure that the selection process for the ARO has been carried out according to your companies processes and any deviations have been properly documented. Before starting, it is important to understand who will be involved in the process. There is nothing more annoying than thinking you have an agreed contract to discover that there is an additional major review required by an institution's legal department! Understand what flexibility you might have internally from both your business partners and legal support. Understanding the non-negotiables e.g., ownership of data, and ensure these are discussed early to save you considerable time and may avoid losing goodwill with the ARO.
3. What type of contract should I use with an ARO?
It is very common to negotiate a master services agreement with CROs and other specialist suppliers. This enables contracts for new projects to be put in place quickly using work orders or statements of work. This approach is less common with AROs possibly because projects are often one-off collaborations or projects with the same ARO may vary considerably with different contractual language requirements. Talk to your internal business partners to understand the future collaboration potential so that the most appropriate contract model can be utilised. It may be that a strategic partnership document may help frame the relationship and expectations from both sides.
4. How can I avoid delays in getting my ARO contract signed?
Unfortunately contracts with AROs often take longer than other service providers. There are a variety of reasons for this but there are things you can do to help speed up the process. Firstly,

see if it is possible to start negotiations based on their template. If this is not possible adapt your template (or at least key wording) to recognise the differences between AROs and CROs.
See PCMG ARO guidelines for more details (add link)

5. How can I make sure payments to my ARO don't raise compliance concerns?

Unlike CROs, there are additional considerations when making payments to AROs. Some AROs will be classed as healthcare organisations (HCOs) under the EFPIA definitions and/or Teaching Hospitals under the Sunshine Act. Payments and other transfers of value will need to be reported and may face additional scrutiny from regulators. There may be compliance concerns (both internally and externally) where large payments are being made to an important customer and so it will be important to establish that a fair price for legitimate services has been paid.
Our key recommendation is to ensure that you understand your company's policy and processes regarding payments to AROs at the outset of any interaction and follow any applicable fair market value (FMV) process.
See PCMG ARO guidelines for more details (add link)

6. My ARO wants to bill me for FTE time but my manager wants a fixed unit price contract. How can I resolve this?

For many academic institutions research is not viewed as a commodity and their primary focus will be to cover costs for headcount with standard institutional overheads added on top. Even if your preferred contract model is unit cost based, it makes sense to understand the FTE model being proposed before looking at different financial and contractual models. Here are some thoughts on FTE models:

- They allow transparency for financial reporting and compliance (see above). HCP time can be assessed according to FMV benchmarks.
- Ask for details on the percentage of time being spent on your project – do they have other academic duties? Are they working on other research projects? Ensure the proposal reflects the hours on your project.

Once you have completed this assessment, investigate how such FTE costs can be converted into your preferred contractual approach (e.g. fixed unit costs). Ask for costings to be supplied in a different format, but be aware that this may not be possible or sensible in all cases.

7. How can I reduce the chance of performance issues with my ARO?

Monitor performance carefully at the start of the project to pick up early signals of issues, especially from quality of data. Schedule frequent meetings during this time and ensure key performance data is collected on time and visible to all. In some cases, data may be more milestone driven as you may not have enough data to generate formal KPIs.

8. I have to work with this ARO but I am worried they have gaps in capabilities. How can I manage this?

Due diligence is important for all third parties involved in clinical trials but is particularly important for AROs that may have less clinical trial experience and where there is less choice of who to partner with

Some pharma companies will invest both time and resources to help the ARO build specific capabilities or deliver to the appropriate standard. For example, this can include support for systems validation and appropriate QMS.

Ensure any concerns over capabilities are incorporated into your risk management plan and monitor carefully.