

# CONTRACT RESEARCH ORGANISATION (CRO)



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# USE OF CRO

## 1. Tactical Outsourcing

Individual studies or selected activities within a study are contracted to a CRO only when in-house resources become inadequate because of an un fore-seen study or a reduction in staff.

## 2. Maximum Outsourcing

With this strategy the sponsor outsources nearly all of its clinical development activities to CROS.

## 3. Strategic Outsourcing

The sponsor conducts Phase I and early Phase II studies, and hires CROS to conduct larger and routine studies.

# CRO PROBLEMS

Problems with contract studies can often be traced by:-

- 1.The wrong CRO is selected.
2. Sponsors often make the mistake of assuming that a CRO that has performed well on one study will be equally capable of conducting a study in a different therapeutic area.
- 3.Some sponsors mistakenly assume that all CROs are the same.- The sponsor fails to articulate its needs clearly.
4. Sponsors sometimes issue a request for proposal (RFP) with little more than a protocol outline, and expect CROS to guess what services and resources are required.

# THREE CRITICAL STEPS TO ENSURE SUCCESS WITH A CRO

- In order to ensure successful outsourcing, the sponsor should focus on three critical steps:-
  1. Determine accurate study specifications
  2. Select the right CRO
  3. Manage the study

# DETERMINE STUDY SPECIFICATION

- Study specifications are a list of activities required to initiate, conduct, analyze, and report the results of a clinical study.
- They include tasks that will be performed in-house and those to be contracted out to one or more CROS.
- Importance of Accurate Study Specifications
- Study specifications are an essential element of the sponsor's request for proposal (RFP) and the CRO's proposal.
- Accurate study specifications also enable the CRO to perform a 'reality check' on the sponsor's expectations.
- This analysis also provides useful criteria for selecting the right CRO.

# SELECTING THE RIGHT CRO

The three most important criteria for selecting a CRO are:

1.Capability

2.Compatibility

3.Cost

- MANAGING THE SPONSOR-CRO RELATIONSHIP The sponsor should follow three principles for managing an outsources project:-
- Clarify the role and responsibilities of the sponsor and CRO.
- Define and use 'performance metrics' to measure study progress.
- Ensure efficient communication between the sponsor and CRO.

# SPONSOR ROLE AND RESPONSIBILITIES

- Define the study specifications
- Provide information to the CRO
- Monitor results Recognize 'red flags'
- Resolve problems
- Approve changes in "scope"



# CRO ROLES AND RESPONSIBILITY

- Evaluate feasibility
- Provide adequate, well managed staff
- Conduct study activities
- Manage processes
- Bring problems and proposed solutions to the sponsor's attention
- Ensure that the solutions are cost-effective

# CONCLUSION

- More effective contracting of clinical drug-development activities to CROs can be achieved by applying the following methods:-
- Use a strategic approach to outsourcing Follow the three principles for achieving success with define accurate study specifications
- select the right CRO and manage the study.
- CROs:-Select CROs according to the three Cs: capability, compatibility and cost.
- Evaluate the CRO's resource allocations.

# REFERENCES

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thank you

