

CONTRACT RESEARCH ORGANISATION (CRO)



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INTRODUCTION

- Contract Research Organization (CRO) is a service organization which provides support to the pharmaceutical industry.
- It offers various pharmaceutical research that is essential for conducting clinical trials in the present boom, when various complications are involved in the drug discovery process.
- Various companies are involved in his type of development many examples are the like Lupin, Quintil, Cipla, Zydus, Cadeila.
- They are also conduct these type of trails with the collaboration of many multinational companies and these Indian companies are making space in foreign.

BACKGROUND

- There is a growing reliance by sponsors on contracting out part or all of the work of the clinical trial to a sub-contractor.
- Manufacturers often find that they cannot organize every clinical trial that they require.
- The reasons are many, but commonly reflect.
- limited staff resources pressures of time.
- Subsequently, the field has expanded to include firms in the areas of; - formulation development- stability programs, pharmacokinetic studies ,biostatistics,data management

OVERVIEW OF CRO

- Traditionally, a CRO was viewed by pharmaceutical industry something as an un-acceptable risk, because of lack of confidence in it terms of their qualification, experience and capabilities.
- However, the modern view is that the in- house staff can be kept for "core needs" e.g., designing of study selection of CRO.
- A list of qualified CROS is developed based on:-
- The sponsors needs The range of services provided by CRO
- The therapeutic area of expertise of CRO, and The compatibility with the sponsor

USE OF CRO

Strategies for using CRO typically fall into three categories:

- Tactical outsourcing
- Maximal outsourcing
- Strategic outsourcing

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.

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thank you