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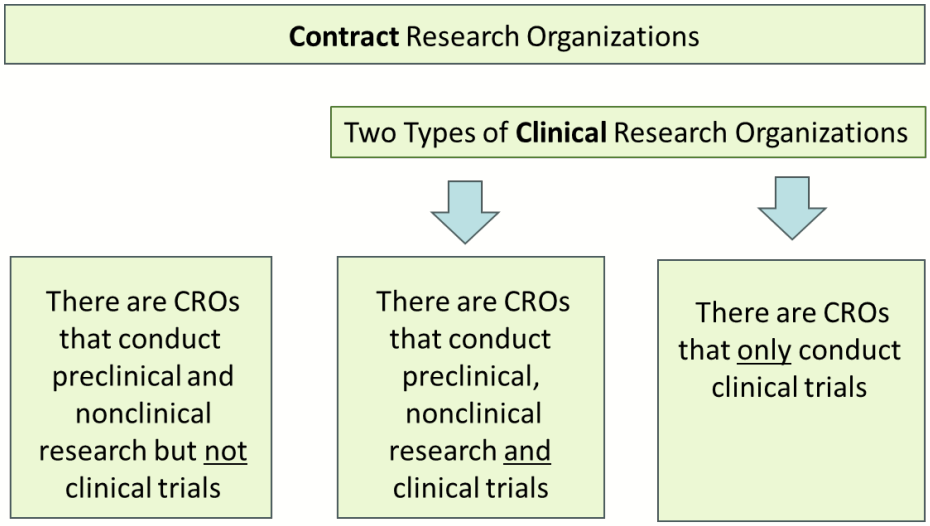
An Innovator's Guide to Choosing a CRO

What is a CRO?

There are two types of organizations that use the acronym CRO: **contract** research organizations and **clinical** research organizations. Since new drug innovators may use one or both types of CROs, both are included in this document.



Contract research organizations are specialized entities that offer research services on a contractual basis to innovators. CROs deliver a broad spectrum of services: drug development, laboratory and lifecycle management, and clinical research. They can provide essential pre-clinical drug development services from pharmacology and toxicology testing to creating drug delivery devices and performing shipping tests; they also often provide expertise in data management, regulatory affairs, and quality assurance.

Contract research organizations play a pivotal role in drug development by offering cost-efficient services compared to in-house development. For small businesses, use of a contract research organization can often accelerate the timeline and reduce the expense associated with evaluating a new drug.

Contract research organizations **nonclinical** research services may include:

- Analytical Method Development and Validation – creating methods to assess drug candidate purity.

- Bioanalytical Method Development & Validation – establishing methods to measure drug concentrations in biological specimens.
- Drug Metabolism and Pharmacokinetic Studies – understanding drug metabolism and interactions with other drugs.
- Pharmacokinetics and Pharmacodynamics Studies – investigating drug absorption, distribution, metabolism, and excretion.
- Pre-formulation and Formulation Development – determining the best dosage form for a drug candidate.
- Stability Testing – assessing drug candidate stability under varied conditions.
- Toxicology Studies – evaluating drug candidate safety.

Clinical research organizations are specifically engaged to manage the filings for and conduct of clinical research and clinical trials. In some instances, they may also provide non-clinical support (as described above) prior to initiating a clinical campaign.

Clinical research organizations services may include:

- Biostatistics – providing statistical analysis of clinical trial data.
- Data Management – collecting, managing, and analyzing the data generated during the trial.
- Logistics – this includes managing the supply chain for the trial, such as shipping and storing investigational products.
- Medical Writing – preparing study protocols, investigator brochures, patient-informed consent forms, clinical study reports, and regulatory submission documents.
- Monitoring – includes monitoring the trial's progress to ensure it is conducted, recorded, and reported under the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirements.
- Pharmacovigilance – monitoring and reporting adverse events and other safety information during the trial.
- Project Management – coordinating multiple aspects of the trial, from planning to execution to close-out.
- Regulatory Affairs – includes preparing and submitting documents for regulatory approval and ensuring regulation compliance throughout the trial.
- Site Management – this involves overseeing the day-to-day operations of the trial sites, including training site staff, managing supplies, and ensuring data quality.

- Site Selection and Activation – includes identifying, evaluating, and selecting suitable sites for the trial. They also handle the administrative tasks required to activate these sites.

To summarize, CROs furnish extensive non-clinical and clinical research services for evaluating new drugs efficacy and safety. Selecting a CRO compatible with your company's needs and timeline is a critical activity for most small biotech or pharma companies. It is important to tailor selection of a CRO to the therapeutic you are developing - small molecule drugs, biologics (e.g., recombinant proteins, mAbs) or cell/gene therapies.

Since small molecule drugs are typically easier to develop than biologics and cell/gene therapies, selecting a CRO for small-molecule drugs is often based on the cost of development and the quality of the product. Typically, biologics and cell/gene therapies are more complex to develop. As a result, selecting a CRO for biologics and cell/gene therapies is often based on the CRO's expertise in handling complex development processes, regulatory compliance, and quality control.

Innovators should consider multiple criteria and multiple potential providers/partners when choosing a CRO. The resources linked below can help you understand the critical criteria for your specific drug, as can the information included in the Contract Research Organization checklist and the Clinical Research Organization checklist.

Resources:
FDA: Step 2: Pre-Clinical Research
FDA: Pre-clinical Assessment of Investigational Cellular and Gene Therapy Products
CFR: 21 CFR Part 58 - Good Laboratory Practice for Non-clinical Laboratory Studies
FDA: Step 3: Clinical Research
FDA: Basics About Clinical Trials
FDA: Regulations: Good Clinical Practice and Clinical Trials
Article: CROs vs CMOs, and CDMOs: What's the difference between the three?