# Working with CROs

Relationships with contract research organizations (CRO) should not be considered a data in, data out process. Once a CRO has been selected, it is critical to set mutually agreed upon expectations upfront, build requirements for quality into contracts, and closely monitor studies to ensure an optimal outcome for your project. Here we highlight the most important considerations for contracting agreements and best practices to maintain a strong working relationship with a CRO throughout your study.

## Master service agreement (MSA)

The MSA is an over-arching legal agreement that establishes the obligations and services to be provided throughout your relationship with a CRO. Consult your legal counsel to review the terms and conditions of any agreement. Most universities will have template agreements in place. Resources like ADDF ACCESS and Science Exchange offer consolidated contracting to streamline this process.

- **Essentials** – Almost all MSA's will include language around confidentiality assurances, intellectual property rights, exclusivity around drug target, materials transfer, warranties, liabilities, indemnities, and termination. Pre-negotiated cancellation costs and potential add-on costs should be included.
- **Subcontractor transparency** – The CRO is responsible for any subcontracted services and a separate MSA for subcontracted CROs is not needed.
- **Business model** – The MSA should specify the appropriate model for your program. The vast majority of early-stage programs will use fee for service, or sometimes the full-time equivalents (FTE) model, which pays for full-time employees. Alternative models, like risk-sharing agreements, are used sparingly, but would be more relevant for later stage *in vivo* efficacy or investigational new drug (IND)-enabling studies at biotech companies. This model generally offers reduced service fees in exchange for a share of your company's equity.
- **Data handling** – The MSA should outline the systems that are in place for data management and security.

## Statement of Work (SOW)

The SOW is a mutually agreed upon work plan, with clear goals and objectives for each project at a CRO. SOW's should include clear scientific milestones and deliverables with detailed project tasks, and should outline cost breakdowns, payment schedules, communication schedules, and reporting requirements.

## Maintaining Communication

Interactive communication throughout the project is absolutely essential. Some key ways to ensure a strong working relationship with a CRO include:

- **Developing personal chemistry and trust** – The study director is critical for problem solving and the success of the program. The study director should feel comfortable with the approach and communicating with the sponsor about problems and mistakes as they occur.
- **Setting up regular calls on a standing schedule** – Talk with the project management and technical staff frequently. CROs should be open to talking weekly, or even more frequently, depending on the nature of the project.
- **Asking to see the data often** – A good CRO should regularly provide analyzed data reports and raw data (i.e. LC/MS spectra, plate reader files, images). You should also expect to receive regular written reports, progress updates, and presentations of results.

## Managing the Data

CROs should have safeguards in place that ensure your data is accurate and securely stored. Key areas that you should monitor closely throughout your project include:

- **Handling** – Confirm who will have access to your data and how data input is tracked?
- **Consistency** – Discuss quality control in detail. How robust are the assays? Are the data reproducible? Are controls consistently used for all assay iterations and, are the control data always analyzed?
- **Storage and Security** – Expect CROs to store data and compound structures in secure databases. Are there firewall networks, regular backup procedures, and off-site backups? Assess physical security policies for data and compounds: where are they stored, who has access, do the freezers have backups, and how are compounds transported?
- **Data transfer** – Possible security breaches can occur when data are transferred to and from the CRO and internally within the CRO. Make sure each of your CROs have robust safeguards in place.

**References**

Lane, R.F., et al. *Optimizing the use of CROs by academia and small companies.* Nat Rev Drug Discovery. 2013, 12: 487-8.