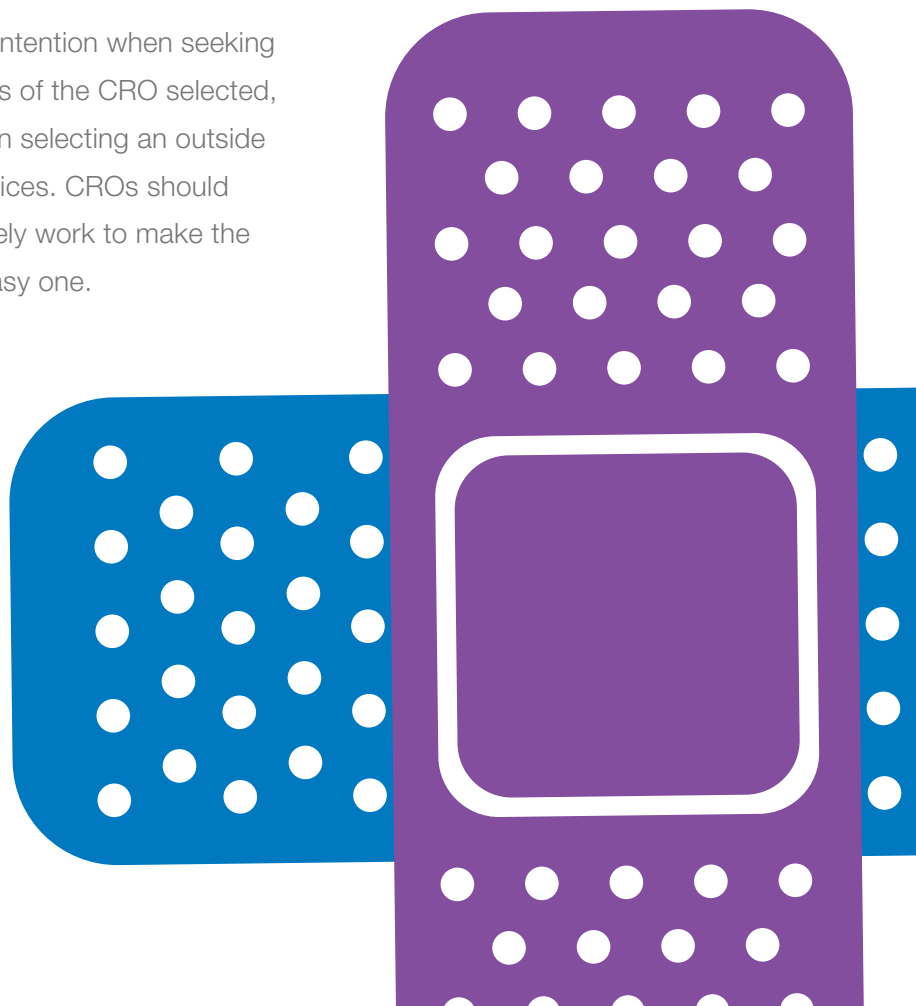


A traditional pain point is used to highlight displeasure with a certain product or service.

Though this term may not be all that common in clinical research, it is useful in highlighting concerns that have been communicated to us over the years about hiring a CRO for clinical support services.

These pain points become a point of contention when seeking outside support from a CRO. Regardless of the CRO selected, a sponsor is taking a “leap of faith” when selecting an outside resource to provide clinical support services. CROs should be aware of these pain points and actively work to make the outsourcing decision for sponsors an easy one.

Some of the “pain points”
that we consistently hear in our
discussions with sponsors.



▶ Staff Turnover Rate

Contract Research Organizations (CROs) continue to struggle with talent retention as employee turnover rates remain around the 24% mark. There are many reasons that can be cited that contribute to this number, but from a sponsor's perspective high turnover is a real source of concern.

▶ Consistency

Sometimes due to high turnover, and sometimes due to readjusting schedules, consistency in the assigned study team becomes a problem. Many sponsors have stated that they have seen dramatic shifts in approach due to personnel shifts, which creates problems for their studies.

▶ Creativity

Many clinical research professionals lack a true understanding of the regulations and how to apply them across various study types. This can lead to the "We've always done it this way" mentality, which may not be appropriate for the situation at hand. There is an absence of creativity and critical thinking skills.

▶ Dealing with Independent Contractors

Many sponsors use independent contractors for various clinical support services. This approach can also lead to inconsistency in approach, and can overburden the sponsor with managing several additional personnel. In addition, there can be communication issues depending on how well the independent contractors work together.

▶ Costs

Embarking on a clinical trial is a very expensive proposition already. A major cost can be the ongoing budget management of the chosen CRO.

▶ Communication

One of the challenges a sponsor faces in hiring a CRO is ensuring strong communications amongst the entire clinical team. Because they are not a part of the team, the level of interaction can suffer.

▶ Compliance

The importance of fully understanding regulatory requirements and expectations for compliance is paramount. Each and every year, FDA warning letters cite inadequate monitoring and failure to secure compliance as top findings.

▶ Data Quality

The end-goal of every trial is product approval. Study hypothesis testing and the determination of investigational product safety and effectiveness depends upon evaluable data.

▶ Regulatory Foundation

Lacking a basis for making decisions while on site can lead to an inconsistent approach.

How many pain points have you experienced?

[Contact us](#) today to share your concerns with using outsourced CROs and let IMARC Research discuss how our approach is different.



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